DEPOSITION AND INDEX

OF

ANDREW LEE, M.D.

MARTIN v PFIZER

MDL Case No. 1724
Case No. 06-cv-1064 (PAM)

ORIGINAL

Tuesday, January 13, 2009

Krista K. Irish, CSR, RPR, RMR
IRISH REPORTING, INC.
305 - 10th Avenue
Hiawatha, IA 52233
319-393-5050
E-mail - kirish@irishreporting.com

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:	)	
	)	MDL Case No. 1724
Viagra Products Liability	)	
Litigation	)	
	)	
----------	)	
Richard Martin,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 06-cv-1064(PAM)
	)	
Pfizer, Inc.,	)	
	)	
Defendant.	)	

VIDEOTAPED DEPOSITION OF ANDREW LEE, M.D., taken on Tuesday, January 13, 2008, commencing at 1:05 p.m., at Hotel Vetro, 201 South Linn Street, Iowa City, Iowa, before Krista K. Irish, Certified Shorthand Reporter of the State of Iowa.

Krista K. Irish, CSR, RPR, RMR
IRISH REPORTING, INC.
305 - 10th Avenue
Hiawatha, IA 52233
(319) 393-5050

APPEARANCES:

J. Jason Richards and Neil D. Overholtz, Appearing Telephonically, of Aylstock, Witkin, Kreis & Overholtz, P.L.L.C., Attorneys at Law, 803 North Palafox Street, Pensacola, Florida 32501, Attorneys for the Plaintiff.

Daniel E. Becnel, Junior, of the Becnel Law Firm, L.L.C., Attorneys at Law, P. O. Drawer H, 106 West 7th Street, Reserve, Louisiana 70084, Attorney Appearing Telephonically for the Plaintiff.

Lori B. Leskin and Mark D. Spatz, of Kaye Scholer, L.L.P., Attorneys at Law, 425 Park Avenue, New York, New York 10022-3598, Attorneys for the Defendant.

John W. Borg, District Court Judge, Retired, 6612 Limerick Drive, Edina, Minnesota 55439, Special Master.

ALSO PRESENT: Mark DeMeulenaere, videographer

INDEX

EXHIBITS

EXHIBITS (Cont'd.)

PROCEEDINGS

THE VIDEOGRAPHER: My name is Mark DeMeulenaere of Veritext. The date today is January 13th, 2009, and the time is approximately 1:05 p.m. The deposition is being held in the office of Hotel Vetro boardroom located at Linn Street, Iowa City, Iowa. The caption of this case is Richard Martin, plaintiff, versus Pfizer, Inc., defendant, in the Viagra products liability litigation. The name of the witness is Dr. Andrew Lee. At this time the attorneys will identify themselves and the parties they represent, after which our court reporter, Krista Irish of Veritext, will swear in the witness, and we can proceed.

MR. SPATZ: Mark Spatz for Pfizer.

MS. LESKIN: Lori Leskin, Pfizer.

MR. RICHARDS: Jason Richards for Mr. Martin.

MR. BECNEL: Daniel Becnel for the plaintiffs' committee.

MR. OVERHOLTZ: Neil Overholtz for the plaintiff.

JUDGE BORG: John Borg, special master.

Ms. Court Reporter, would you swear the witness, please.

Page 6

(The witness was duly sworn at this time.)
JUDGE BORG: Dr. Lee, have you been deposed before?
THE WITNESS: Yes.
JUDGE BORG: Okay. If a question is put to you, and you don't understand it, you can go ahead and say that, and whoever's examining will do their best to make it clearer for you. If there is someone who says objection, please don't answer the question until I tell you whether or not you can, and if you need any breaks, let us know. All right.
THE WITNESS: Thank you.
JUDGE BORG: Ms. Leskin, you may proceed.
MS. LESKIN: Thank you, judge.
(Lee Exhibit 1 was marked for identification by Attorney Leskin.)

Page 7

ANDREW LEE, M.D., was called as a witness and, being first duly sworn, testified as follows:
DIRECT EXAMINATION
BY MS. LESKIN:
Q. Dr. Lee, I'm going to hand you what we've marked as Lee Exhibit 1 (indicating), and this is what we received from plaintiff's counsel representing to be your current curriculum vitae. Is this, in fact, a true and correct copy of your current curriculum vitae?
A. Yes.
Q. If you'll look at the upper left-hand corner, it says last revision was November 17th, 2008?
A. Yes.
Q. Have you made any changes to your CV since November 17th, 2008?
A. Yes.
Q. Okay. What else has been added to your CV since that time?
A. I presented at two additional meetings and --
Q. And what meetings?
A. The Columbia University Grand Rounds in New York City, and Current Concepts in Atlantic City,

Page 8

and I've published a few more papers since this.
Q. Okay. Let's take those one at a time. You said you presented at Columbia University Grand Rounds?
A. Yes.
Q. When was that?
A. Just this past week.
Q. And was there a particular topic you presented on?
A. Yes, neuroimaging studies and emergency cases in neuroophthalmology.
Q. Were there any written materials or presentation or PowerPoint slides or articles that went along with that presentation?
A. No.
Q. You also said you presented at Current Concepts in Atlantic City, New Jersey?
A. Yes.
Q. And when was that presentation?
A. On Saturday.
Q. And what was the topic of your presentation at that meeting?
A. Infectious optic disk edema, and ten easy mistakes to avoid in neuroophthalmology.
Q. And were there any written materials that

Page 9

went along with that presentation?
A. No.
Q. Was there a PowerPoint slide you used -- PowerPoint slides you used?
A. Yes.
Q. Okay. And do you have copies of those presentations?
A. Not on me.
Q. Okay. Did either the presentation at Grand Rounds or the presentation at Current Concepts involve Viagra?
A. No.
Q. Did it involve arteritic ischemic optic neuropathy?
A. Yes.
Q. And did it involve causes of nonarteritic ischemic optic neuropathy?
A. No.
Q. You also said you've published additional papers since November 17th, 2008. What papers have you published since then?
A. Some chapters and books and some monographs were submitted, but nothing related to ischemic optic neuropathy or Viagra.
Q. What were your book chapters about?

A. General neuroophthalmology topics.
Q. And which textbooks -- or books, I should say?
A. One is an online guide called the Hyperguide. The other is a textbook that we're writing on geriatric ophthalmology.
Q. And was the subject of nonarteritic ischemic optic neuropathy discussed in either of those chapters?
A. Yes.
Q. And is Viagra mentioned in either of those chapters?
A. Not Viagra, no.
Q. Are any of the PDE-5 inhibitors mentioned in either of those chapters?
A. No.
Q. Are causes of nonarteritic ischemic optic neuropathy included in those chapters?
A. No. It's just very general information.
Q. And I keep saying nonarteritic anterior ischemic optic neuropathy. If I abbreviate that as N A I O N or NAION, will you understand what I'm referring to?
A. Yes.
Q. Okay. Good, because I think that will make

all of us much happier, including the court reporter. Does the CV that we've marked as Exhibit 1 as modified -- You can hold on to that. Does the CV that we've identified as Exhibit 1 with the addendums we've just identified accurately reflect your education and training?
A. Yes.
Q. Does it accurately reflect your employment history?
A. Yes.
Q. And does it accurately reflect your medical training?
A. Yes.
Q. And your medical appointments?
A. Yes.
Q. Does it accurately reflect your publications?
A. Yes.
Q. Do you currently practice in terms of seeing patients?
A. Yes.
Q. Okay. And you practice as a neuroophthalmologist, is that correct?
A. Yes.
Q. And you're board certified as an

ophthalmologist?
A. Yes.
Q. How often do you -- Strike that. How many patients do you see in a given year would you estimate?
A. Three thousand.
Q. And those are all through the University of Iowa?
A. Yes.
Q. And how many of those approximately three thousand patients have nonarteritic anterior ischemic optic neuropathy?
A. Maybe two or three hundred.
Q. And of those two or three hundred patients with NAION, how many of them have you personally diagnosed with NAION?
A. We either make the primary diagnosis or provide a second opinion confirming that diagnosis.
Q. And how many new cases of NAION do you estimate you see in a given year?
A. Probably fifty to a hundred.
Q. Now, you've been at Iowa since about 2000, correct? Do I remember -- Did I read that correctly?
A. Yes.
Q. And before that you were at Baylor, right?

A. Yes.
Q. And has the nature of your practice changed since you've come to Iowa compared to what you were doing at Baylor?
A. No.
Q. And has the number of patients you've seen changed?
A. A little less.
Q. Less patients here?
A. Yes.
Q. And would the number of patients with NAION that you've seen changed?
A. No.
Q. Do you teach?
A. Yes.
Q. What courses do you teach?
A. We teach our residents and the medical students. They rotate through, so there's not really a course. And then I do national courses like I just explained to you at Columbia and Atlantic City for practicing physicians and residents in other parts of the country.
Q. Do you have a course that you teach within the medical school?
A. No.

Page 14

Q. Do you conduct research?
A. Yes.
Q. What types of research projects do you have currently ongoing?
A. A number of clinical research projects. A clinical research project is one that involves the use of patients and performing tests on them and then making some analysis of the data, so we have a number of projects. My area of interest is optic nerve, so looking at optic nerve diseases.
Q. Do you currently have any studies going on regarding NAION?
A. We've been asked to participate but have not recruited for yet two studies to look at the possible cause and effect relationship of these agents with ischemic optic neuropathy.
Q. Okay. Now, you said you've been recruited. Have you signed up to actually participate in those studies?
A. We've gone to the preliminary meetings where the study design is unfolded and the recruitment is explained, et cetera, but we haven't actually recruited any patients yet. It's not to that level yet. The other study is just in the question phase, would you be willing to participate,

Page 15

and we send in survey data, how many patients have we seen with the condition, how many do you see in a year, similar to what you've already asked me.
Q. Okay. The first study that you just mentioned, who's sponsoring that study?
A. One is Pfizer, and the other, I think, is Bayer, but I -- I can't remember exactly, because that other one is just in the asking stage, and I didn't look at -- there were -- no protocol was distributed with it, so I'm not sure if they're -- it's just a public relations firm that is doing the initial part, because no company logo was attached to this; it was just a outsourced survey form.
Q. And was there -- Let's talk about the study sponsored by Pfizer first. What is the hypothesis that that study is investigating?
A. If there's a cause and effect relationship that can be excluded from the use of this agent in relationship to nonarteritic anterior ischemic optic neuropathy.
Q. Now, when you say "this agent," you're referring to PDE-5 inhibitors?
A. Yes.
Q. Okay. And who is the primary investigator at the University of Iowa?

Page 16

A. We don't -- We're not to that level yet of signing.
Q. Okay. Did you personally attend the presentation by Pfizer?
A. Yes.
Q. Okay. And did you receive a copy of the protocol?
A. We did look at the -- what was -- the preliminary. I don't know if this would be the final or not --
Q. Okay.
A. -- because we did not sign up for the study yet, for me, because I'm moving to Houston, Texas.
Q. Oh, you're moving to Houston?
A. (Witness nods head.)
Q. When are you moving to Houston?
A. April 1st.
Q. Okay. And what institution are you going to be affiliated with?
A. I'm going to be the chairman of ophthalmology at the Methodist Hospital in the Texas Medical Center, Houston, Texas.
Q. Do you know whether Methodist Hospital is participating in this study?

Page 17

A. Probably will not be participating, because it's too late for us to catch up to the rest of the people.
Q. Do you know whether there is anyone at the University of Iowa who will be participating in this study?
A. I don't know that, because my colleagues -- After we went to the preliminary meeting, they did not tell me whether they were going to participate or not.
Q. Okay. So as of today, you don't know one way or the other whether the University of Iowa will, in fact, participate in the Pfizer study, is that fair?
A. I think it's unlikely that they will.
Q. Okay. And do you know why that's unlikely?
A. I think there have been questions about the study design that have made a lot of neuroophthalmologists changed their minds about participating.
Q. And are these questions that you raised?
A. These were raised at the -- both at the presentation meeting and also have been circulated on our Internet chat site.
Q. Is that the NANOS chat site?

Page 18

A. Yes.
Q. But sitting here today, you don't know one way or the other whether they will, in fact, sign up, is that fair?
A. I don't know one way or the other, but I doubt it.
Q. Okay. Now, you also made reference to the the protocol design circulated by Bayer --
A. I think that's the --
Q. -- or the study invitation?
A. Yeah, there's a study outsource company that -- They did not provide the protocol.
Q. Okay. But your belief is that that is being sponsored by Bayer?
A. I think so.
Q. Okay. And is that -- What is the hypothesis of that study?
A. Same study, but different agents, I think.
Q. Okay. Have you had the opportunity to review a preliminary protocol from the Bayer study?
A. No.
Q. Do you know whether -- how the design of the Bayer study compares to the Pfizer study?
A. No.
Q. Do you know whether there have been any

Page 19

questions raised regarding the design of the Bayer study?
A. No, because we didn't get to see the protocol yet, so --
Q. Do you know whether the -- Methodist Hospital will be participating in the Bayer study?
A. It would be unlikely that we would participate.
Q. And why is that likely?
A. It's unlikely, because we --
Q. Oh, unlikely or likely?
A. Unlikely.
Q. Oh, Okay.
A. -- because we are starting a new department, and I would just have started there April 1st. By the time we caught up there would be -- It's unlikely that we would have enough time to catch up.
Q. And do you know whether any of your colleagues at the University of Iowa will be participating in the Bayer study?
A. I think it's unlikely that they will participate.
Q. Okay. But you don't know one way or the

Page 20

other?
A. No.
Q. Other than those two studies, are you aware of any other studies regarding NAION that are currently undergoing at the University of Iowa?
A. Not related to --
Q. Not related to the Pfizer or Bayer study we just discussed.
A. Yeah, there are many.
Q. Okay. Are there any studies going on that relate to the causation of NAION?
A. No.
Q. Are there any studies going on in animals regarding NAION?
A. Yes.
Q. Okay. And do those studies relate to the causation of NAION?
A. Yes, some.
Q. Okay. And are you participating in those studies?
A. No.
Q. Okay. Have you had input into the design of those studies?
A. No.
Q. And the study -- the other studies

Page 21

regarding NAION that you've discussed, do you have -- are you personally involved in any of those studies?
A. Yes.
Q. Okay. What studies are you personally involved in regarding NAION currently?
A. We look at photographs and also measurements of nerve fiber layer with a machine called optical coherence tomography, which is OCT. Those are the predominant studies that are ongoing with this entity, but they're not causality studies.
Q. And what is the purpose of those studies?
A. To look at predictive value of certain parameters that we see in the patients to see if we can predict who's going to lose vision or keep their vision, how much vision they're going to lose, these types of things.
Q. Have you done any studies of blood flow at the University of Iowa?
MR. RICHARDS: Objection, form.
JUDGE BORG: Overruled.
A. I haven't done any blood flow studies myself, but there have been blood flow studies done.
Q. At Iowa?
A. Yes.
Q. And have you done any studies that look at

Page 22

the different technologies available to measure ocular blood flow?
A. Have I done studies?
Q. Yes.
A. No.
Q. Have you participated in any studies of that?
A. No.
Q. Have you done any epidemiological studies regarding the prevalence of NAION?
A. No.
Q. Have you done any epidemiological studies to determine whether various agents can cause NAION? I'm asking you personally.
A. No.
Q. Okay. Have you personally been involved in any studies of Viagra?
A. No.
Q. Have you personally been involved in any studies of any of the PDE-5 inhibitors?
A. No.
Q. Now, you told me that you are board certified in ophthalmology, right?
A. Yes.
Q. And you're a licensed to practice medicine

Page 23

here in Iowa, I assume, is that right?
A. Yes.
Q. Where else are you licensed to practice medicine currently?
A. Texas.
Q. Anywhere else?
A. No.
Q. Now, you're not an expert in hypertension, is that fair to say?
A. I am not.
Q. And you don't treat hypertension in your patients, right?
A. No.
Q. And you don't diagnose hypertension in your patients?
A. We sometimes diagnose hypertension.
Q. Do you personally diagnose hypertension?
A. Yes.
Q. Okay. And how do you go about diagnosing hypertension in your patients?
A. A patient might have an eye finding that is related to hypertension, but they don't know it, we check their blood pressure, can make the diagnosis, call the internist, they confirm the diagnosis, they treat.

Page 24

Q. Okay. So if a patient comes in who you find has hypertension, you would refer them to someone else to determine the appropriate treatment for that patient, correct?
A. Yes.
Q. And you don't advise other doctors how to treat patients with hypertension, is that right?
A. We don't advise them how to treat hypertension, but we might advise them on ocular side effects of treatments if we see them in their patient.
Q. You're not an expert in urology, right?
A. I'm an expert in neuroophthalmology. Some of that has overlap with neurology, but I am not a neurologist.
Q. Let me -- You may not have heard my question, or I may have not spoken clearly. You're not an expert in urology?
A. Oh, urology.
Q. Urology.
A. I'm definitely not an expert in urology.
Q. Okay. And you don't treat erectile dysfunction in your patients, correct?
A. I do not treat erectile dysfunction.
Q. And you don't diagnose patients with

Page 25

erectile dysfunction?
A. We might make the diagnosis if they tell us a history compatible, but we would refer that patient.
Q. To a urologist or an internist?
A. Yes, whoever they have chosen to treat with.
Q. Someone outside the ophthalmology department?
A. Yes.
Q. Okay. And you've never prescribed a treatment for erectile dysfunction to a patient, have you?
A. No.
Q. And you've not discussed the options for treatment for erectile dysfunction of patients, have you?
A. If they have ischemic optic neuropathy, we might give our advice.
Q. Okay. You're not an expert in epidemiology, are you?
A. No.
Q. And you're not an endocrinologist, right?
A. No.
Q. And you don't diagnose diabetes, correct?

Page 26

A. We sometimes diagnose diabetes, but we would treat --
Q. Okay. Under what circumstances would you diagnose diabetes?
A. We might see diabetes in the eye, diabetic retinopathy. We would draw the red blood studies, blood sugar or hemoglobin A1c, make the diagnosis, refer for confirmation and treatment.
Q. Okay. But you wouldn't treat the patients for diabetes?
A. We don't treat the diabetes.
Q. Now, have you ever worked for any pharmaceutical company?
A. No.
Q. Have you ever worked under contract for a pharmaceutical company?
A. No.
Q. Have you ever received grants from pharmaceutical companies?
A. No.
MR. RICHARDS: Judge Borg, if I could just clarify. She asked -- The last question have you ever received grants from pharmaceutical companies, is she referring to him personally or the University of Iowa?

Page 27

Q. Is there a distinction between that in your mind?
A. Yes, the University receives many study grants --
Q. Okay.
A. -- and we might participate.
Q. Okay. Have you applied for grants from any pharmaceutical company, you personally on behalf of the University of Iowa?
A. I've been an investigator where I was not the principal investigator of drug studies to look at the ocular portions, but I have not been the principal recipient of the grant. We just get paid to do the exams and send them back.
Q. Okay. And that -- But that work is funded by a grant from a pharmaceutical company?
A. Several of those are pharmaceutical supported.
Q. And is the fact that some of your work is funded by a grant from a pharmaceutical company, does that fact affect how you go about doing your examination?
A. No.
Q. Does that affect how you do your work?
A. No.

Page 28

Q. Does that affect any of the conclusions you draw about your patient?
A. No.
Q. Does it effect any diagnosis you might make?
A. No.
Q. Have you ever received any speaking fees from any pharmaceutical company?
A. No.
(Lee Exhibit 2 was marked for identification by Attorney Leskin.)
Q. I've handed you what we've marked as Lee Exhibit 2 (indicating), and I know you have a -- I saw you have a copy that you brought with you, which is a copy of the subpoena that was served on Mr. Overholtz on your behalf in this litigation. When did you first receive a copy of the subpoena?
A. I think just right before today's scheduled, maybe two days before.
Q. This week?
A. Yes.
Q. And how did you receive that?
A. I believe it came by fax, but I'm not sure. It just appeared in my outbox. My secretary opens the mail, so I'm not sure if it was a fax or mail.

Page 29

Q. Okay. And if you look at the third page of the document we've marked as Exhibit 2, you'll see there's something called Attachment A.
A. (Witness complies.) Yes.
Q. Were you aware that the subpoena asked you to bring certain documents with you?
A. I looked at it. I tried to bring everything on here.
Q. Okay. Tell me what you did to comply with the request in the subpoena.
A. The things I had I brought with me.
Q. Okay. And you've already identified for us, I know, a copy of your prior litigation list that we had received --
A. Yes.
Q. -- a copy of the subpoena --
A. Yes.
Q. -- a copy of your expert report in this litigation --
A. Yes.
Q. -- a copy of an article you authored with Ms. Newman -- with Dr. Newman --
A. Yes.
Q. -- correct? And now you have -- Is there anything else from that pile in front (indicating) of

Page 30

you that I missed?
A. No.
Q. I also note that you brought three letters from Zimmerman Reed, correct?
A. Yes. Some were me to them.
Q. I'm sorry?
A. Some were --
Q. Oh, you're right. You're right. One letter from Zimmerman Reed to you from Ms. Hansen dated October 24th, 2008, enclosing records of Richard Martin, correct?
A. Yes.
Q. And a check for $1100 as a retainer, correct?
A. Yes.
Q. And then you brought with you a letter dated October 29th, 2008, from you to Ms. Hansen at Zimmerman Reed --
A. Yes.
Q. -- regarding the Martin versus Pfizer case. Reviewing the records, this required three hours to review the record and formulate an opinion and includes the time to discuss the opinion with your office. This consumed the two-hour retainer, and I would be most obliged if you could send a fee check

Page 31

in the amount of $550, and then you have a copy of the receipt, which I would assume indicates you, in fact, received that additional $550, right?
A. Yes.
Q. Okay. And the third letter is dated November 12th, 2008, again from you to Neil Overholtz at Zimmerman Reed, indicating that you had reviewed the depositions of Mr. Martin and Ms. Martin requiring three hours to review the record and to formulate an opinion and includes the time to discuss the opinion with your office. If a check can be sent in the amount of sixteen -- $1,650. Did you, in fact, receive a check in that amount?
A. Normally we put the check receipt on there --
Q. So there's no check receipt --
A. -- so it might still be floating around in the office somewhere.
Q. Okay. So to your knowledge it's your normal course that if -- when you receive a check for payment, you attach it to your letter?
A. I attach the receipt.
Q. You attach the receipt to your letter?
A. Yes.
Q. So the fact that there is no receipt, does

Page 32

that indicate to you you have not yet been paid?
A. Or it's in the University mail system or on my secretary's desk somewhere.
Q. The address that you've requested the check be sent to is 205 Black Springs Circle, Iowa City, Iowa. Is that your work address?
A. No.
Q. That's your home address?
A. Yes.
Q. So did you, in fact, receive a check?
A. I don't know. I have to go check.
Q. Okay. Have you sent any additional invoices to Mr. Overholtz or anyone at Zimmerman Reed since November 12th, 2008?
A. I don't think so.
Q. You also brought with you -- And we'll come back to these letters (indicating). You also brought with you it looks like two green hanging folders.
A. Yes.
Q. Can you identify what those are?
A. The records they sent and the depositions.
Q. Okay. Now, the records they sent were for Mr. Martin?
A. Yes.
Q. Okay. And the depositions were of whom?

Page 33

A. Mr. and Mrs. Martin.
Q. Any other deposition transcripts besides Mr. and Mrs. Martin's?
A. I don't think so.
Q. It looks like there are three clipped things there.
A. I think one is a duplicate. Mrs. Martin again.
Q. Okay. So you have two copies of Mrs. Martin's and one copy of Mr. Martin's deposition?
A. Yes.
Q. Did you receive any other deposition transcripts from plaintiff's counsel?
A. Not that I know of.
Q. Okay. And the medical records from Mr. Martin that you received, do you know which treaters those included?
A. They're in this (indicating) thing if you want to look at it.
Q. Okay. If I can take a look at that.
A. (Witness complies.)
Q. Now, I want to go back to the letters you brought. Now, the first letter here -- Do you mind if I mark these as exhibits, and we'll put stickers

Page 34

on the original; is that okay?
A. That's fine.
Q. Okay. We'll make copies before you leave.
A. Okay.
(Lee Exhibits 3, 4 and 5 were marked for identification by Attorney Leskin.)
Q. I'm going to mark as Exhibit 3 -- Lee Exhibit 3 the letter dated October 24th, 2008 (indicating); as Exhibit 4 the letter dated October 29th, 2008, and the attached check receipt; and as Lee Exhibit 5 your letter dated November 12th, 2008. This just makes it easier for us to identify it on the record. Okay? So starting with Exhibit 3, this letter, as you can see, is dated October 24th, 2008.
A. Uh-huh.
Q. How long prior to receiving that letter on or about October 24th, 2008, was the first time you spoke with anyone from Zimmerman Reed or on behalf of the plaintiff about this case?
A. How long -- I'm sorry.
Q. How long -- That letter is dated October 24th, 2008, correct?
A. Yes.
Q. Do you know how long after October 24th,

Page 35

2008, you first received that letter?
A. No.
Q. Was it sometime around October 24th, 2008?
A. Yes.
Q. Okay. How long before October 24th, 2008, did you first speak to anyone representing Mr. Martin?
A. I don't know that. I'm not even sure I did. Maybe someone called and said here's the records, here's the issue, would you like to review the records, something like that. I can't remember dates.
Q. Okay. So prior to receiving this letter from Ms. Hansen, you don't recall any conversation with Mr. Overholtz or Ms. Stacy Hauer?
A. No, normally someone would call --
Q. Okay.
A. -- in advance and say this is what we have, would you be interested in looking at the record --
Q. Okay.
A. -- but I can't tell you the date or who.
Q. Okay. Can you tell me approximately how long it was?
A. No.
Q. Was it a matter of weeks; was it a matter

Page 36

of months?
A. I don't know.
Q. Was it in 2008?
A. I would guess it was probably within weeks, but I --
Q. Okay.
A. I don't know.
Q. So to your best recollection it was sometime in October 2008?
MR. RICHARDS: Objection to form. He said he doesn't know.
A. I don't know. I'm sorry.
Q. Okay. Could it have been in January 2008?
MR. RICHARDS: Objection to form.
Q. I'm just trying to better understand when --
A. I would be just guessing, but, yeah, maybe.
Q. Okay.
A. Sometime plus or minus two months.
Q. Okay. That's fair.
MR. OVERHOLTZ: Boy, he's sitting there, he's our expert, none of this stuff even matters, and you're wasting your time.
MS. LESKIN: Thank you.
MR. RICHARDS: And just so you know, Neil,

Page 37

Judge Borg has stepped out of the room. He just --
MS. LESKIN: No, he's back in the room.
JUDGE BORG: I'm back.
MR. RICHARDS: He just came back, but he didn't hear the objection.
MS. LESKIN: Okay. I didn't have a question on the table, so there's no objection, just a statement for the record that he made.
MR. RICHARDS: Just so he knows.
MR. BECNEL: I join in the objection.
MS. LESKIN: If I can get a question out, it would be very helpful.
MR. BECNEL: Yeah, but you had one out, and Neil objected, and now I object.
Q. Dr. Lee, do you keep any notes of any of the consults that you have from a litigation standpoint? So when lawyers call you, do you keep a note or a record of the conversations you have with them?
A. No.
Q. Do you know whether you spoke with Mr. Overholtz or Ms. Hauer in the first instance?
A. No.
Q. Do you recall the substance of the conversation that you had with them?

Page 38

A. No.
Q. And so sometime in October of 2008 the records just showed up on your -- in your mailbox, is that fair?
A. No. Normally they say we have a case, would you like to look at it, and I say send it or not.
Q. Okay.
A. But I don't recall --
Q. But you don't recall any of the substance of the conversation you had prior to receiving the records in October 2008?
A. That's correct.
Q. Do you know what records you received with this letter that we've marked as Exhibit 3?
A. I think all of these (indicating) came with that, but I don't know for sure.
Q. The medical records and the deposition transcripts?
A. I think the depositions came later.
Q. Okay. We marked as Exhibit 4 the letter dated October 29th, and you said you spent three hours reviewing the record and formulating an opinion, and it includes the time to discuss the opinion with your office, and that's the letter sent

Page 39

to Ms. Hansen, who is identified as a paralegal to Mr. Overholtz, correct?
A. Yes.
Q. Okay. What do you recall, if anything, of the conversation you had about the records you reviewed that you referred to in this letter?
A. Those records that I reviewed?
Q. Whatever records you reviewed at the time you sent this letter.
A. It's very similar to the opinions I gave as a summary.
Q. Okay. And that was the report that you've given in this case?
A. Yes.
Q. Okay. At any time -- Now, did you talk to Mr. Overholtz or to someone else in the office?
A. I don't remember.
Q. Do you know if it was male or female?
A. Sometimes it was Mr. Overholtz, but sometimes it was associates, but I can't remember who they were.
Q. Did you ever speak to Mr. Richards before?
A. I think so.
Q. Then Exhibit 5 references your review of the depositions of Mr. and Mrs. Martin that took

Page 40

three hours and included time to discuss your opinion, again, with Mr. Overholtz or others in the office. Do you recall anything about the substance of that conversation that's referenced in Exhibit 5?
A. No, but I think similar to the opinion summary.
Q. At what point in time were you asked to take your opinion and prepare a report?
A. After this date (indicating) sometime, but I don't know the exact date.
Q. November 12th, 2008?
A. Yeah.
Q. Other than the deposition transcripts of Mr. and Mrs. Martin and the medical records that you were provided, was there anything else about Mr. Martin that you reviewed?
A. No.
Q. Was there anything else about Mr. Martin that you discussed with the plaintiff's counsel?
A. I'm sure we talked about a lot of things about Mr. Martin, but I don't remember all the questions they asked.
Q. Okay. Did you talk about the deposition testimony given by any of his treating physicians?
A. I don't think so.

Page 41

Q. Did you talk about the reports given by any other expert in this litigation?
A. I don't think so.
Q. Were you aware that there were other experts in this litigation?
A. I was aware there were other experts, but I don't know who they are.
Q. Were you told anything about the status of the litigation?
A. No.
Q. How long did it take you to write the opinion in this case?
A. Like actually type it up?
Q. Yes.
A. It probably took an hour and a half maybe.
Q. Did anyone help you do that --
A. No.
Q. -- or did you do it yourself?
A. Just me.
Q. And did you provide a draft to any of the plaintiff's counsel before you signed it?
A. I think I sent an e-mail nonheadered copy, yes.
Q. And did they give you any comments?
A. I don't think so.

Page 42

Q. And to whom did you send that e-mail?
A. The Overholtz office.
Q. Did you keep a copy of what you sent?
A. No.
Q. If you wanted to check to see whether you you still had a copy of the prior draft of your report, where would you check?
A. The deleted files. I don't know.
Q. Did you make an effort to look for the version you had e-mailed them?
A. No.
Q. Were you aware that that had been requested in the subpoena that you were served with?
A. I didn't have it, so I can't remember what I don't have.
Q. Well, did you look to see if you had it?
A. I guess I could get the IT guy to go into the deleted files, but normally I can't do that.
Q. Okay. But do you have a specific recollection of deleting that file?
A. Normally it just overwrites the old one, you know, so you have to go back and get the --
Q. Well, but you indicated that you sent an e-mail to plaintiff's counsel with an earlier version of your report.

Page 43

A. Yeah, they just overwrite on top of it.
Q. On top of the e-mail?
A. No, on the -- I don't keep the version I sent to them. They kept it.
Q. Did you keep the e-mail you sent to them?
A. No.
Q. You delete out of your send folder? I'm asking if you have the e-mail that you sent to plaintiff's counsel.
A. I don't keep any of those.
Q. Okay. Did you check to see in your outbox as to whether any e-mails still existed?
A. None of those exist.
Q. Did you check in your outbox to see if any existed?
A. Yes, because our mailbox fills up quite quickly, so you have to delete all the sends and all the deleted e-mails; otherwise, you can't use it. It's a very small box.
Q. Did any of plaintiff's counsel give you any comments on any -- on the drafts that you sent them?
A. I think they said good.
Q. Did they ask you to make any changes?
A. I don't think so.

Page 44

Q. How many drafts did you send to them by e-mail before the final version?
A. I think just one.
Q. And how long before the final version was sent did you send this to them?
A. I think right away. They said good and yes.
(Lee Exhibit 6 was marked for identification by Attorney Leskin.)
Q. I'll show you what's marked as Exhibit 6 a copy of the expert report that we received in this case, and that is, in fact, your expert report, correct?
A. Yes.
Q. And that's your signature on the front page?
A. Yes.
Q. And at the time you signed this front page was it attached to the report that you prepared?
A. Yes.
(Lee Exhibit 7 was marked for identification by Attorney Leskin.)
Q. I've marked as Exhibit 7 (indicating) a copy of the deposition list that we were provided, 1996 through 2008, and you prepared this and gave

Page 45

that to plaintiffs, correct?
A. Yes.
Q. Okay. And that's a -- This appears to be a complete copy of the list, correct?
A. Yes.
Q. You don't have any dates listed on here. Does this go in chronological order with the most recent first, or chronological order with the most recent last, or are they not in chronological order?
A. I don't mean to be vague, but chronologic is not accurate, because they're overlapping, and some are done, and some are active, some are --
Q. Okay. So let me ask --
A. Like you mean from when I received the record?
Q. Let's use that as our date, yes.
A. It's probably oldest to newest then.
Q. Okay. So the most recent case other than this one that you've worked on is Ramsey versus Frank, is that correct?
A. Most recent would be, yeah, Ramsey versus Frank.
Q. Okay. And then this case comes after that --
A. Yes.

Page 46

Q. -- in time?
A. And after this I'll add this on here.
Q. You'll add what?
A. I'll add this on there.
Q. Okay. And have there been any other cases that you've been retained in since this list was prepared -- or provided to us?
A. That I've given deposition in?
Q. Yes.
A. No.
Q. Have there been any other cases that you've been retained to prepare a report?
A. No. There are other cases we're at various stages of looking at the records.
Q. Okay. How many of these cases that you have listed in Exhibit 7 involve a product liability case? Do you know what I mean by that?
A. Yes.
Q. Okay.
A. Not very many. Maybe one.
Q. Okay. Which one?
A. But I can't remember which one it is. Maybe it has a company name on it, though. Aventis Pasteur.
Q. What page? That's the Ken Lewis case?

Page 47

A. Yes.
Q. Is that -- The attorney is Ken Lewis?
A. Yes.
Q. And who did you testify for in that case, which side?
A. I don't know.
Q. Do you know the product that was involved in that case?
A. No.
Q. When was that case?
A. I don't know.
Q. Would you have any records that indicate when that case was pending?
A. No. After the case is closed I destroy the records.
Q. Do you have any records or any kind of record that would indicate who Mr. Lewis was representing in that case?
A. No. After the case is closed I destroy everything.
Q. Okay. And sitting here today you don't have a recollection one way -- which side you testified on?
A. No.
Q. Do you remember the issue that was involved

Page 48

in that case?
A. No.
Q. Do you remember the injury that was involved in that case?
A. I'm sure it was neuroophthalmologic related, but I can't tell you what it was.
Q. Do you know what the allegation was in that case?
A. No.
Q. Has your testimony ever been excluded by a court?
A. No.
(Lee Exhibit 8 was marked for identification by Attorney Leskin.)
Q. I'm going to hand you what we've marked as Exhibit 8, which is a letter dated October 29th, 2008, purporting to be from you to Ms. Ann Hansen.
A. Yes.
Q. Did you, in fact, write this letter?
A. Yes, including the misspelling.
Q. Which misspelling?
A. The spell check made neuro into neuron.
Q. But this is a letter that you wrote and you prepared, correct?
A. Yes.

Page 49

Q. And did you prepare it on or about October 29th, 2008?
A. Yes.
Q. And what was the reason for preparing this letter?
A. I think Mr. Overholtz's office asked us to send this letter.
Q. Did they explain to you why they asked you to send this letter?
A. No.
Q. As of October 29th, 2008, had you, in fact, reached an opinion in this case?
A. Yes.
Q. And after October 29th, 2008, did you review any other materials besides Mr. Martin's medical records?
A. The depositions.
Q. And did that make any difference in your opinion?
A. No.
Q. Are there any -- Is there anything else that you relied upon in preparing your opinion in this case?
A. No.
Q. Did you ever talk to Mr. Martin?

Page 50

A. No.
Q. Did you ever examine Mr. Martin?
A. No.
Q. Did you ever speak with Mrs. Martin?
A. No.
Q. And to be clear, you've never spoken with any of the other expert witnesses in this case, correct?
A. I have not.
Q. Do you know Dr. Heyreh?
A. Yes.
Q. Have you worked with Dr. Heyreh?
A. Yes.
Q. Okay. Have you spoken with Dr. Heyreh about the Viagra litigation?
A. No.
Q. Are you aware that Dr. Heyreh was an expert for plaintiffs in this litigation?
A. No.
Q. No one told you that?
A. No.
Q. Do you know Dr. Pomeranz; Howard Pomeranz?
A. Yes.
Q. Have you spoken to Dr. Howard Pomeranz?
A. About this?

Page 51

Q. Well -- Yes, about this.
A. No.
Q. Were you aware that Dr. Pomeranz was an expert for plaintiffs in this litigation?
A. Yes, today.
Q. When did you learn that?
A. In the hallway.
Q. From whom?
A. The attorney (indicating).
Q. Mr. Richards?
A. Yes.
Q. And what were you told about Dr. Pomeranz's role in this litigation?
A. I don't know. His name just came up, but --
Q. Were you told that his opinion had been excluded from this litigation?
A. I didn't know that.
Q. Have you ever spoken to Dr. Pomeranz about Viagra?
A. Yes.
Q. Do you know Dr. Gerald McGwin?
A. No.
Q. Do you know Dr. Aruna?
A. No.

Page 52

Q. Do you know Dr. Williams?
A. No.
Q. Do you know Dr. Neal Sher?
A. Neal Sher I know --
Q. Okay.
A. -- but only peripherally. I don't know him personally.
Q. Have you spoken to Dr. Sher about this litigation?
A. No.
Q. Were you aware that he's an expert for the plaintiffs in this litigation?
A. No.
Q. Do you know a Dr. Witt?
A. No.
Q. Do you know Dr. Cheryl Blume?
A. No.
Q. Had you ever worked with Mr. Overholtz prior to this litigation?
A. No.
Q. Had you ever worked with anyone from the Zimmerman Reed firm prior to this litigation?
A. I don't think so.
Q. Do you know how they came to contact you for this litigation?

Page 53

A. No.
Q. Do you know Dr. Simmons Lessel?
A. Yes.
Q. Have you spoken to Dr. Lessel about this litigation?
A. No.
Q. Were you aware that he was an expert for Pfizer in this litigation?
A. No.
Q. Have you looked at his report that he gave in this litigation?
A. No.
Q. Do you know Dr. Stephen Kimmel?
A. No.
Q. Do you know Dr. John Mulcahy?
A. No.
Q. Do you know Dr. Daniel Shames?
A. No.
Q. During any of the conversations you had with Mr. Overholtz or anyone else from any of the law firms representing plaintiff -- Mr. Martin -- representing plaintiff -- Let me strike that. Let me start again. During any of the conversations you had with any of plaintiff's lawyers in this case did you talk about any plaintiff other than Mr. Martin?

Page 54

A. Yes.
Q. And who else did you talk about?
A. I can't remember the names.
Q. Okay. And what were you told about these other plaintiffs?
A. They had similar allegations.
Q. Okay. Did the name Richard Stanley get mentioned to you?
A. Yes.
Q. And what were you told about Mr. Stanley?
A. Similar allegation.
Q. Okay. And were you told anything about Mr. Stanley's medical history?
A. Yes.
Q. What were you told?
A. I don't remember all the -- because I didn't have the whole thing to look at.
Q. Were you asked to write a report in Mr. Stanley's case?
A. No.
Q. Were you asked to give an opinion in Mr. Stanley's case?
A. Yes.
Q. Okay. And did you, in fact, give an opinion in Mr. Stanley's case?

Page 55

A. Yes.
Q. And what opinion did you give in Mr. Stanley's case?
A. The strength of the case was not as good as the Martin case.
Q. Did you ever receive any medical records from Mr. Stanley?
A. I think we had limited -- limited summary-type records.
Q. When you say "summary-type records," who prepared the summary?
A. I don't know. I didn't have all the records, just the ones they showed me.
Q. And when did they show those to you?
A. I don't remember the dates.
Q. Did you receive those in the mail the same way you received these?
A. I believe so.
Q. And I apologize if I asked this question. Do you know who prepared the summary?
A. No.
Q. Did anyone provide you a written summary of records in this case?
A. No.
Q. Do you know whether there were any other plaintiffs that you specifically discussed with plaintiff's counsel?

Page 56

A. I don't think there were others. I think maybe they had given various scenarios, but I don't remember their names.
Q. Okay. Now, we talked a little bit about nonarteritic ischemic optic neuropathy, which we've been calling NAION for short. I want to talk just a few minutes about what NAION is. Okay?
A. (Witness nods head.)
Q. Yes?
A. Yes.
Q. Okay. Now, it's a type of optic neuropathy, right?
A. Yes.
Q. And that means that it's an injury to the optic nerve?
A. Yes.
Q. And the A, the anterior, that means it's the anterior portion of the optic nerve that's affected, right?
A. Yes.
Q. And the anterior portion is the very front of the optic nerve, correct?
A. Yes.

Page 57

Q. It's the part that's right behind the eyeball, is that right?
A. It's where the eyeball and the eye nerve meet (indicating).
Q. Okay. And that's referred to sometimes as the optic nerve head?
A. Yes.
Q. And the reference to ischemia indicates that it's an ischemic event, right, that occurs?
A. Yes.
Q. And that means a loss of blood to the optic nerve, right?
A. It might not be loss of blood.
Q. Okay. What else might that mean?
A. The oxygen-carrying capacity might be reduced.
Q. So it may not necessarily be because of a loss of blood, but for some reason oxygen isn't getting to the optic nerve head, right?
A. Yes.
Q. And, in fact, the cause of NAION is not really known, is that fair?
A. It's ischemic, but the exact cause is not known.
Q. There have been some hypotheses published,

Page 58

right?
A. That's correct.
Q. Okay. But no one has yet determined with any specificity what the cause is?
A. It's probably multifactorial, so it cannot be assigned basically to one thing.
Q. We have about eight minutes left on the video before they have to change, so I just want to ask you a couple more questions, and then we're going to take a short break, change the video and come right back. Okay?
A. All right.
Q. Which vessels -- Which blood vessels feed the anterior portion of the optic nerve?
A. Well, the central retinal artery's on the top, but the posterior ciliary arteries are the ones that go to the back part of the anterior portion of the nerve.
Q. And those branch off of the ophthalmic artery, correct?
A. Yes.
Q. Which branches off of the carotid artery?
A. Yes.
Q. Which is part of the main aorta coming up from the heart, is that right?

Page 59

A. Yes.
MS. LESKIN: Okay. We're going to take a short break, and we'll change the videotape.
JUDGE BORG: Mr. Videographer, what time?
THE VIDEOGRAPHER: 2:01.
(A brief recess was taken.)
JUDGE BORG: Back on. Time?
THE VIDEOGRAPHER: 2:06 p.m.
Q. (By Ms. Leskin) Dr. Lee, before we took a break we were talking about NAION, and I just want to talk a little bit about the progression -- the natural progression of NAION. What's the first indication that a patient will have that he has NAION?
A. Loss of vision.
Q. How much time elapses between the insult to the optic nerve and the patient noticing a loss of vision?
A. We don't know that, because we only see the patients when they lose their vision.
Q. Do you agree that for each case of NAION there is some variation from patient to patient?
A. Yes.
Q. The ages vary, right?
A. Yes.

Page 60

Q. The location of the visual defect -- the visual field defect changes?
A. Not that it changes. It's just variable between patient.
Q. That's what I meant. It varies from patient to patient, right?
A. Yes.
Q. And the progression within each patient varies?
A. Most don't progress, but some do.
Q. And the extent of vision loss varies from patient to patient?
A. Yes.
Q. And the final visual acuity is different, right, from patient to patient -- it varies from patient to patient?
A. Yes.
Q. Once NAION -- Once the insult occurs does NAION come and go, or is it just always going to be there now?
A. It comes and stays.
Q. And does the visual loss that the patient experiences as a result of the NAION, does that come and go, or does that either progress or get better, or is it consistent -- That's a bad question. Let me

Page 61

start that again. When a patient has vision loss from NAION, does the vision loss that they experience come and go, or is it consistent?
A. It comes and stays, but they might have variability from day to day in their function.
Q. But if a patient has a visual field defect, will their vision suddenly become normal before it gets worse?
A. No, it won't be normal, but they'll have better days and worse days, better days and worse days.
Q. And over what period of time does that occur?
A. Years.
Q. In the acute stage, when the -- The optic nerve is swollen, right?
A. (Witness nods head.)
Q. Yes?
A. Yes.
Q. For the court reporter's sake, you need to answer verbally. I know we have a video camera, but she (indicating) needs to take down words. We'll just remind you if you forget.
A. Thank you.
Q. And during that acute stage can there be

Page 62

this coming and going of visual loss?
A. It's not that it comes and goes. It just has fluctuation.
Q. If you look into a person's eye, can you tell what caused their NAION?
A. No.
Q. If you look into a person's eye, can you tell how the disease is going to progress in that patient?
A. No.
Q. Now, the natural -- We talked about the natural progression. You said it comes -- the vision loss comes and stays, but sometimes over time it may -- vision loss may improve, right?
A. It might improve.
Q. Or it might get worse?
A. Or it could get worse.
Q. And it's common that sometimes people who have NAION in one eye will get NAION in the second eye?
A. That's uncommon.
Q. Uncommon?
A. Uncommon.
Q. Okay.
MS. LESKIN: I apologize. I don't have a

Page 63

copy of this exhibit (indicating). If I find one, I'll give it to you.
(Lee Exhibit 9 was marked for identification by Attorney Leskin.)
Q. I'm going to mark as Exhibit 9 a chapter called Neuroophthalmology, which is chapter 7 in a book called Prognosis of Neurological Disorders. You can show it to counsel.
A. (Witness complies.)
Q. And I'd like to direct your attention to page 100 of the exhibit --
MR. RICHARDS: I still have the exhibit in front of me.
MS. LESKIN: Okay.
Q. First let me direct your attention to page 97 of the exhibit, which is actually page 97 of the book; it's not 97 pages long. This is a book chapter you wrote, correct --
A. Yes.
Q. -- with Paul Brazis, B R A Z I S?
A. Yes.
Q. And if you look at the page marked 100, you'll see there's a section of the chapter called nonarteritic anterior ischemic optic neuropathy, right?

Page 64

A. Yes.
Q. Okay. And if you look at the left-hand column of that book chapter --
A. Yes.
Q. -- of that page, I should say, the second paragraph reads, although it is rare for nonarteritic AION, N A, hyphen, A I O N, to recur in the same eye, it may involve the fellow eye in 10.5 percent to 73 percent of cases, with most authors citing contralateral eye involvement in 25 percent to 40 percent of cases. Did I read that correctly?
A. Yes.
Q. And that was based on the literature that you reviewed in preparing this article, correct?
A. Yes, but this is not up to date.
Q. Okay. What is the more -- What do you rely on for more up-to-date figures?
A. The ischemic optic neuropathy decompression trial.
Q. Okay. And what is a number in that trial?
A. It's more like 12 to 14 percent, something like that.
(Lee Exhibit 10 was marked for identification by Attorney Leskin.)
Q. We're going to mark as Exhibit 10 --

Page 65

You can give that (indicating) to counsel, please.
A. (Witness complies.)
MR. BECNEL: Lori, did you attach that chapter as an exhibit?
MS. LESKIN: Yes, Exhibit 9.
MR. BECNEL: Okay. I can't see what you're doing, that's why.
MS. LESKIN: Understood.
Q. Exhibit 10 is an article by Nancy J. Newman, et al, entitled The Fellow Eye in NAION: Report From the Ischemic Optic Neuropathy Decompression Trial Follow-Up Study. Is that the article you're referring to, Doctor?
A. Yes.
Q. Okay. And if you look at page 320 of that article --
A. (Witness complies.)
Q. -- in the right-hand column it says over the course of the IONDT patient follow-up, 14.7 percent of patients at risk experience new NAION in the fellow eye, right?
A. Yes.
Q. And is that the data that you were referring to?
A. Yes.

Page 66

Q. Okay. So in this study at least almost 15 percent of the patients experienced NAION in the other eye, right?
A. Yes. It's much lower than we used to think.
Q. And the time frame that Dr. Newman followed up her patients was a median of about -- a little over a year, right?
A. I think this is a five-year data study.
Q. Well, if you look at page 320 again --
A. I --
Q. You're right. I misspoke. The time interval between the original onset and new -- Strike that. The time interval in her study between the original onset and the event in the second eye, that median time interval was 1.2 years, right?
A. I think that's about right.
MR. RICHARDS: I'm going to ask if Ms. Leskin is going to ask some questions relating to the paper, that he be allowed the chance to at least review the paper if he needs to to make sure he's familiar with it so he can answer the questions.
MS. LESKIN: He can take as much time as he wants. If he --
Q. If you can't answer my question, and you

Page 67

need time to review the paper, please tell me, and I'll be happy to give you as much time as you need.
JUDGE BORG: It doesn't sound like there's an objection to the objection.
MS. LESKIN: Nope.
MR. RICHARDS: Do you need time to review the paper?
THE WITNESS: Not for the questions she's asked so far.
Q. And if you look at that right-hand column, that first full paragraph, in fact, Dr. Newman, et al, writes, the median interval between study eye NAION, using enrollment date, and occurrence of new NAION in the fellow eye was 1.2 years, right? That's what she wrote?
A. (Witness nods head.)
Q. Yes?
A. Yes.
MR. RICHARDS: Are you looking at the actual page, Dr. Lee?
Q. Page 320.
A. Which page are you on?
Q. I'm sorry. Page 320, the right-hand column under the table, the first full paragraph. Do you see where I read that from?

Page 68

A. This one right here (indicating)?
Q. It says -- Right. The paragraph that starts the median interval.
A. Yes, I think you read it -- what it says.
Q. Okay. And she reported that the median interval between original NAION and new NAION was 1.2 years, correct?
A. Yes.
Q. And the range she reported was from sixteen days up to six years, right?
A. Yes.
Q. And she goes on to report that nearly half of the fellow eye NAION events, which she says is twenty-two out of forty-eight of them, occurred in the first year following the original event, right?
A. Yes.
MR. RICHARDS: I was just going to -- You're paraphrasing, right? You're not quoting directly?
MS. LESKIN: That's correct. If he has any problem with my paraphrasing, the doctor is more than capable of checking that.
Q. But I paraphrased that correctly, right?
A. Yes.
Q. Now, to be clear, and please take your time

Page 69

to read as much of the article as -- specifically this section on risk of NAION in the fellow eye as you need, but the numbers that Dr. Newman report are the patients who develop NAION in the second eye during the course of her follow-up, correct?
A. Yes.
Q. And she starts off this section saying that study neuroophthalmologists determined at the baseline examination that eighty patients, or 19 percent of total, had had an episode of NAION in the fellow eye before enrollment, correct?
A. Yes.
Q. And concludes the section reporting that 30.6 percent of the patients based -- had -- Strike that -- that 30.6 percent of the patients had NAION in the second eye, correct?
A. In the second eye, but they had it before -- some of them had it before they entered the study.
Q. Correct. So that patients -- 30.6 percent of the patients, though, had at some point in their lives developed bilateral NAION, correct?
A. I'm sorry. You'll have to rephrase that.
Q. Sure. The NAION -- the ischemic optic neuropathy decompression trial --

Page 70

A. Yes.
Q. -- was a study of patients with NAION, correct?
A. Yes.
Q. And they enrolled patients based on a diagnosis of new NAION in one of their eyes, correct?
A. That's correct.
Q. And then they followed them up?
A. Yes.
Q. Okay. Eighty of the patients that they recruited into the study, they were recruited based on a NAION event in their second eye?
A. That's correct.
Q. So that 19 percent of the patients involved in the study entered the study with bilateral NAION, correct?
A. That's correct.
Q. And of the patients who enrolled in the study with one eye only affected, 14.7 percent of those patients developed NAION during the course of follow-up in the study, correct?
A. That's correct also.
Q. And when you look at the study population as a whole, at the end of the study she reports that a hundred and twenty-eight of the four hundred and

Page 71

eighteen patients in the study, which is 30.6 percent, had NAION in both eyes by the end of the study?
A. That's true, but some of them came with it, so they're lumping two groups that have nothing to do with each other.
Q. I'm just looking at the total number of patients that had bilateral NAION by the end of the study regardless of when the onset was, because that --
A. No, that's not legitimate.
Q. Okay.
A. Because if you come into the study, and you already had it, that doesn't -- You can't lump that with the ones that developed it during the study period, because they already had it when they entered into the study, so there's apples and oranges. You can't -- You can't lump them together.
Q. Okay.
A. They cannot be used for incidence number, because they already came with it. Incidence is an occurrence that occurs over a time period, prospectively.
Q. Okay.
A. Anybody that comes into the study with the

Page 72

event, they don't count, because they already had their event before.
Q. But they had had bilateral NAION.
A. Yes, but you can't combine these two groups. Even though they have, it's interesting, but it's not meaningful, because they already had it when they came in, so you cannot say anything about incidence with that number the way you phrased it, bilateral. It's true, it is a fact that they had bilateral, but so what. It has no bearing on the incidence number.
Q. But Dr. Newman reports that of a hundred and -- of four hundred and eighteen patients in the the study, one hundred and twenty-eight of them had bilateral NAION by the end of the study; that's what she reports, correct?
A. No, not by the end of the study. Some of them already had one eye beforehand. They don't count for anything.
Q. One hundred and eighty-eight of the four hundred and eighteen patients in the study had bilateral NAION?
A. That's true.
Q. Okay.
A. That is a statement of fact, but --

Page 73

Q. That's right. I've got --
A. -- it has no bearing on the incidence number, so --
MS. LESKIN: Move to strike --
A. I just want to make sure you didn't combine the apples and the oranges, because --
JUDGE BORG: Dr. Lee, the lawyers -- There are certain rules here, and the lawyers can ask you leading questions, and if you have an explanation --
THE WITNESS: Yes.
JUDGE BORG: -- the other attorney can ask you some questions later on --
THE WITNESS: Okay.
JUDGE BORG: -- if they wish to pursue that.
THE WITNESS: All right. I will be quiet then.
JUDGE BORG: Thank you.
Q. And just to be clear, Dr. Lee, again, Dr. Newman, et al, reported that of the four hundred and eighteen patients, one hundred and twenty-eight of them had bilateral NAION, correct?
A. That part I agree with.
Q. Now, NAION we called nonarteritic, correct?
A. Yes.

Page 74

Q. And that's primarily to distinguish it from a disorder known as arteritic anterior ischemic optic neuropathy, right?
A. Yes.
Q. And arteritic anterior ischemic optic neuropathy is an inflammatory condition, correct?
A. Yes.
Q. Also known as giant cell arteritis?
A. Yes.
Q. And the primary method by which you would distinguish between arteritic and nonarteritic is through a blood test, right, called ESR?
A. Well, there are symptoms, there are blood tests and a biopsy of the artery.
Q. Okay. And the symptoms would be pain in the -- pain in the jaw, correct?
A. Headache, pain in your jaw, pain in your scalp (indicating).
Q. Okay. But there are patients with arteritic who don't present with pain or headache, correct?
A. True.
Q. And the blood test you do is called ESR, right?
A. Yes.

Page 75

Q. And that stands for -- and I'm going to mess up the pronunciation, and you'll correct me -- erythrocyte sedimentation rate?
A. That's correct.
Q. Okay. And that basically measures the blood rate at which the red blood cells fall in a test tube in an hour?
A. Yes.
Q. And that's a nonspecific measurement of inflammation in the system?
A. Yes.
Q. If an ESR is negative, is that conclusive evidence against arteritic ischemic optic neuropathy?
A. No.
Q. You also mentioned a biopsy can be done.
A. Yes.
Q. And that's where they take a piece of the vessel of the temporal artery to see if it shows evidence of inflammation, correct?
A. Yes.
Q. If a patient is treated with steroids, does that affect the findings on a biopsy?
A. It might.
Q. And how long does the patient need to have been taking the steroids in order to affect the biopsy?
A. Normally several weeks.
Q. Would you agree with me that the natural history of NAION has been difficult to define?
A. No. We have the natural history now.
Q. And when you say "now" --
A. Because the study was done to show the natural history.
Q. And some of the known risk factors for NAION include age, correct?
A. Yes.
Q. Hypertension?
A. Yes.
Q. Diabetes?
A. Yes.
Q. High cholesterol?
A. Yes.
Q. Smoking?
A. Yes.
Q. Basically those are all conditions that affect the vasculature, correct?
A. Yes.
Q. And if someone is a vasculopath, in other words, they have an injury to their vascular system, they're at risk for NAION, is that right?

Page 76

Page 77

A. Yes.
Q. If a patient came into your office with a diagnosis of NAION, and he was over age fifty with a history of hypertension, increased blood sugars, what would you say caused his NAION?
MR. RICHARDS: Objection to form.
JUDGE BORG: Overruled.
You may answer.
A. There are predisposing conditions, and all of the things you just mentioned are predisposing conditions.
Q. Okay.
A. NAION is a multifactorial disease, so it would be difficult to say one is more than the other.
Q. Okay. But if someone came into your office with that history, and that was the entire history, you wouldn't be surprised that that person developed NAION, would you?
MR. BECNEL: Objection. The hypothetical is not appropriate. All of the factors are not there.
JUDGE BORG: Overruled.
Do you understand the question?
A. I'm sorry. You'll have to repeat it, because --

Page 77

Page 78

Q. Sure. If a patient came into your office over age fifty with a history of hypertension and a history of elevated blood sugars, and that was the entire relevant medical history, would you be surprised that that patient had developed NAION?
A. No.
Q. And that's a pretty typical presentation of NAION, right?
MR. RICHARDS: Objection to form. She's saying that the typical presentation of NAION are -- is only the two examples she gave as a person who had high blood sugar and high cholesterol, right?
JUDGE BORG: Do you understand the question, and are you able to answer it?
THE WITNESS: Yes.
JUDGE BORG: Overruled.
A. Typically has vasculopathic risk factors. The ones you mentioned are some, but not all of the list of potential vasculopathic risk factors.
(Lee Exhibit 11 was marked for identification by Attorney Leskin.)
Q. Okay. I'm going to mark as Exhibit 11 (indicating) and hand to you an article entitled erectile dysfunction drugs and nonarteritic anterior ischemic optic neuropathy written by Andrew G. Lee

Page 79

and Nancy J. Newman from the American Journal of Ophthalmology, October 2005. I know you brought a copy of this article with you as well, Doctor. I take it you recognize this article?
A. Yes.
Q. And this is an article you wrote, correct?
A. I wrote this with Nancy Newman.
Q. Okay. And the American Journal of Ophthalmology is a journal directed to ophthalmologists, correct?
A. Yes.
Q. That's the intended audience of people with expertise in the individual field, right?
A. Yes.
Q. And if you go to the last page of what we've marked as Exhibit 11, you'll see -- That's the front cover of the journal that it appeared in?
A. (Witness complies.) I don't have the same as what you have.
Q. Oh. Never mind. Well, let me ask you this. Your article was an editorial, correct?
A. Yes.
Q. And you were invited to write the article?
A. Yes.
Q. And you understand that under the policies

Page 80

of the American Journal of Ophthalmology, an editorial is intended to be objective and dispassionate, right?
A. It might contain the opinions of the author.
Q. Okay. But it's intended to be an objective assessment of the evidence in forming your opinion?
A. All articles are supposed to be an objective assessment.
Q. You serve on the editorial board of the American Journal of Ophthalmology, right?
A. Yes.
Q. And this editorial was written for this journal, because Dr. Fraunfelder had published an article based on his review of the adverse event database, correct?
A. Yes.
Q. Now, in your article, looking specifically in the left-hand column of the first page of the article, you make reference to adverse effect reports that have been submitted to the FDA?
A. Yes.
Q. Did you personally go to the FDA web site and locate those adverse event reports?
A. Yes.

Page 81

Q. And what you found was as of May 18, 2005, there were forty-three cases of ION reported after PDE-5 use, correct -- PDE-5 inhibitor use, correct?
A. Yes.
Q. And not all of those were Viagra, right?
A. That's correct.
Q. Okay. And you know that sildenafil is Viagra, right?
A. Yes.
Q. And tadalafil is Cialis?
A. Okay.
Q. Were you aware of that?
A. Yes.
Q. And vardenafil, you understand, is Levitra, right?
A. Yes.
Q. Okay. Are you aware of the chemical differences between those three drugs?
A. They have different half-lives and action.
Q. Now, after discussing the cases you wrote, the FDA -- I'm looking at the bottom paragraph in that left-hand column. You wrote, the FDA also readily acknowledges that most, but not all, of these patients had underlying anatomic or vascular risk factors for development of NAION, including, in

Page 82

parentheses, small, cup to disk ratio, quote, crowded disk, age over fifty, diabetes, hypertension, coronary artery disease, hyperlipidemia and smoking, right?
A. Yes.
Q. And that's consistent with your own review of those adverse event reports, correct?
A. Yes.
Q. And you went on to say, the FDA has been careful to state that they cannot currently draw a conclusion regarding cause and effect but that they continue to monitor the situation. Did I read that correctly?
A. Yes.
Q. And then you wrote, although the case reports to date suggest a possible association between NAION and PDE-5 inhibitors, a causal relationship has not been established conclusively.
A. True.
Q. And Dr. Fraunfelder, who's article is in the journal of that same issue, reached the same conclusion, correct?
A. Yes.
Q. And then you went on to write, according to Pfizer, there have been more than one hundred

Page 83

clinical studies of Viagra, more than thirteen thousand patients, and there were no reported cases of NAION in these patients, right?
A. True.
Q. And you don't have any information currently to contradict that, do you?
A. No.
Q. And to your knowledge that's still a correct statement, correct?
A. Yes.
Q. And then you said that there have been over 170 million sildenafil prescriptions given to 23 million men, up to one billion doses, and thus, even if NAION is related to sildenafil use, the rate of attack must be quite low. To your knowledge is that statement still true?
A. Yes.
Q. Then you continued on, spontaneous NAION is relatively common and is the most common acute optic neuropathy in patients over age fifty years. That's still a true statement, correct?
A. Yes.
MR. RICHARDS: I'd like to clarify. Are you referring to -- The first sentence of the previous paragraph says according to Pfizer, and

Page 84

then it goes on. So are you asking if it's a correct statement according to Pfizer or a correct statement according to him personally?
MS. LESKIN: That's not the question I asked.
MR. RICHARDS: Well, it's confusing. That's why I'm asking you to clarify.
JUDGE BORG: Just -- Well, do we have a question to the witness?
MS. LESKIN: No.
JUDGE BORG: Okay.
MR. RICHARDS: No, she just asked him if that was a correct statement, which she --
MS. LESKIN: No, I asked --
MR. RICHARDS: -- which she's going down a list of paragraphs saying is this a correct statement.
JUDGE BORG: I understand what you're --
MR. RICHARDS: I just want to make sure she knows she's talking to Dr. Lee and not --
JUDGE BORG: I understand what you're saying.
Do you understand there's a question to you?
THE WITNESS: Yes. She asked me if that

Page 85

was correct as written.
JUDGE BORG: Okay.
A. Yes, to my knowledge.
Q. Then you went on, going down to where we were, referring to the Johnson and Arnold study. Do you see that?
A. Yes.
Q. And Johnson and Arnold did a population-based study in Missouri and Los Angeles County and estimated an incidence -- an annual incidence rate of 2.3 per hundred thousand for NAION, correct?
A. Yes.
Q. And that study was done in 1994, right -- or published in 1994?
A. Yes.
Q. And then you refer to a study at the Mayo Clinic, correct?
A. Yes.
Q. And that's the Hattenhauer study?
A. Yes.
Q. And Hattenhauer reported an estimated annual incidence of 10.3 per hundred thousand, correct?
A. Yes.

Page 86

Q. And that study was published in 1997, right?
A. Yes.
Q. Since 1997 the population in the United States has gotten fatter and grayer, would you agree with that?
A. Yes.
Q. And you'll agree with me that as the population gets older and heavier, diseases like NAION increase in frequency?
A. Yes.
Q. You go on in the next paragraph, and you said, although the exact ages for all patients taking sildenafil is unknown, it is assumed that they are older aged and harbor vasculopathic risk factors for both erectile dysfunction and NAION. Did I read that correctly?
A. Yes.
Q. And that's because the risk factors for erectile dysfunction overlap with the risk factors for NAION, correct?
A. Yes.
Q. And that's vasculopaths, right?
A. Yes.
Q. And you go on to say, thus, a certain

Page 87

number, several hundred to perhaps a few thousand, of spontaneous NAION events would be expected to occur each year in a population of 23 million older-aged men using sildenafil. Did I read that correctly?
A. Yes.
Q. And that's because of the background rate that would be expected in a population of older men, right?
A. Yes.
Q. And that has nothing to do with what medication -- whether or not they are taking a medication like Viagra?
A. It might have something to do with it.
Q. Okay. But the background rate is to be expected?
A. Yes.
Q. Okay. And you go on to say, in fact, some of these events, depending on the frequency of use of the drug, would fall by chance alone within six to thirty-six hours of taking sildenafil, right?
A. True.
Q. And that's still a true statement?
A. Yes.
Q. It has been suggested that the symptoms of

Page 88

spontaneous NAION are commonly noted upon awakening, perhaps as a result of nocturnal hypotension. That's Dr. Heyreh's theory, right?
A. Yes.
Q. It would, therefore -- continuing to read -- It would, therefore, not be unexpected for the timing of some spontaneous NAION cases to follow the use of sildenafil, a drug frequently used at nighttime. And by "spontaneous NAION," you're referring to what we talked about earlier, your typical case of NAION in a vasculopath person, correct?
A. Yes.
Q. And you conclude that paragraph, recollection, selection and ascertainment bias might also be at play among the retrospective cases reported to date, and the retrospective cases, those are the case reports you're referring to, right?
A. Yes.
Q. What is recollection bias?
A. You tend to remember things that happen close to your vision loss better than you remember things that are not close to your vision loss.
Q. And what is selection bias?
A. Selection bias is when you pick from a

Page 89

certain group of patients; like you don't include all of them, you only pick the ones that complained.
Q. And what is ascertainment bias?
A. That's the person collecting the data only collects specific types of data and doesn't collect all of the data, so you don't really know what the denominator of the number of people you're looking at is.
Q. Turning to the end of your study -- your article, you wrote, further prospective or case-control data will be helpful in the future to determine if the association of NAION is causal or coincidental. Do you see that?
A. Yes.
Q. And as of October 2005 when you wrote this article, you did not know whether the association of NAION and Viagra -- and PDE-5 inhibitor use was causal or coincidental, is that fair?
A. Yes.
Q. Now, in the article you make reference to the FDA alert that was issued, right?
A. Yes.
(Lee Exhibit 12 was marked for identification by Attorney Leskin.)
Q. I'm going to mark as Exhibit 12 a copy of

Page 90

the FDA alert issued July 2005. Is this the alert you're referring to?
A. Yes.
Q. And you'll see the middle of page 1 has in bold what the actual FDA alert is, including information about new labeling for the PDE-5 inhibitor drugs, right?
A. Yes.
Q. And at the bottom, the last two sentences of that paragraph say, we cannot currently draw a conclusion of cause and effect. FDA will continue to evaluate the issue. Did I read that correctly?
A. Yes.
Q. And that's what you were referring to in your article when you quote the FDA -- when you said they were careful to state that they cannot currently draw a conclusion?
A. Yes.
Q. And that's consistent with the conclusion you wrote when you said a causal relationship has not been established conclusively, right?
A. That's correct.
Q. And the FDA underneath that paragraph wrote, this information reflects FDA's current analysis of data available to FDA concerning this

Page 91

drug. FDA intends to update this sheet when additional information or analyses become available. Are you aware of any additional information issued by the FDA on this issue -- on this question?
A. I think there are more cases now.
Q. Okay. But has the FDA changed its analysis of the data?
A. No.
MR. BECNEL: Let me enter an objection. If counsel looks at what the scientists for the FDA have published to the Obama administration --
MS. LESKIN: Your Honor --
MR. BECNEL: Wait a minute. I'm entering an objection.
MS. LESKIN: The only objection is to form at this time.
MR. BECNEL: But, wait, my objection is specific, because it involves fraud and the FDA. Top scientists have notified the Obama administration that they have been inhibited by drug and medical manufacturers, and, in fact, if you look at the New York Times today, it's fully documented, because it just became public.
JUDGE BORG: Okay. The objection is overruled.

Page 92

Do you need the question repeated?
MS. LESKIN: I think so.
Can you repeat the question, please?
MR. BECNEL: And, Judge, I'd like to make that letter to the -- to the Congress and the Obama administration part of the record as an exhibit.
JUDGE BORG: Well, it isn't here. I presume that you can present that to the court at the appropriate time.
MR. BECNEL: Well, I would just like to get a number on it so I can do that, but I can fax it there in two minutes or e-mail it.
JUDGE BORG: Well, there's no way --
MS. LESKIN: Your Honor, any exhibits that are entered into the record should be done by counsel at the time when they are asking questions, not in the middle of my examination.
MR. BECNEL: Well, we've never had fraud before by scientists at the FDA.
JUDGE BORG: Okay. Court Reporter, will you read the question back, please?
Q. Let me ask the question again. Dr. Lee, looking at Exhibit 12 underneath the FDA alert, the FDA wrote, this information reflects FDA's current analysis of data available to FDA concerning this

Page 93

drug. FDA intends to update this sheet when additional information or analyses become available. Sitting here today, are you aware of any updates that the FDA has issued to this alert?
A. No.
Q. If you can look at your CV. We marked that as Exhibit 1.
A. (Witness complies.) Yes.
Q. And if you can look at page 40.
A. (Witness complies.) Yes.
Q. If you look at number 119 on the list, do you see that you are co-chair of the Sally Letson symposium?
A. Yes.
(Lee Exhibits 13 and 14 were marked for identification by Attorney Leskin.)
Q. I'm going to mark as Exhibit 13 a DVD, which I will -- DVD set, which I will retain custody of, but we'll also mark as Exhibit 14 a copy of the cover of the box. So let me hand you Exhibit 14 (indicating), and you can compare that to the original box that's Exhibit 13 (indicating), Doctor, and make sure that it's an original copy. Is that correct?
A. Yes.

Page 94

Q. And Exhibit 13 is a DVD set of the presentations from the Sally Letson Foundation symposium, correct --
A. Yes.
Q. -- that you co-chaired?
A. Yes.
Q. And if you can turn to the table of contents, which is on the back of the DVD box, which is also the second page of Exhibit 14, I'll direct your attention to disk six.
A. (Witness complies.) Yes.
Q. And chapter four is a presentation called Viagra and vision loss: Does sex make you blind? Do you see that?
A. Yes.
Q. You and Dr. Sadun gave that presentation, correct?
A. Yes.
Q. I'd like to take seven and a half minutes and show you -- We've put that DVD into the DVD player. If you can direct your attention to the monitor.
(The DVD was played at this time.)
MR. BECNEL: This is Daniel Becnel. I'm going to object to the use of a video which does not

Page 95

contain a question.
JUDGE BORG: Well --
MS. LESKIN: Pause it.
(The DVD was paused at this time.)
JUDGE BORG: Yeah, hang on. I presume -- Well, that's a fair question. Are there going to be questions that follow this video?
MS. LESKIN: There will be plenty of questions following the video.
JUDGE BORG: Okay. Please proceed.
MS. LESKIN: Turn the volume up, please.
MR. BECNEL: Object to the special masses ruling on the use of videos in a deposition.
MS. LESKIN: Go ahead.
JUDGE BORG: Okay. Proceed.
(The DVD was played at this time.)
MS. LESKIN: I know we have to change tapes before we do. Let me just ask you one question. That was you giving that presentation, correct?
MR. RICHARDS: I would object to the introduction of the tape. I don't know if we ever got any notice of the documents that they planned on using for this deposition, and maybe counsel can confirm that, whether we did or not, as required by the order.

Page 96

JUDGE BORG: Here's the deal. The objection is overruled. Your objection is preserved. You make it to the court when and if that opportunity arises, but for purposes of the deposition it's going to be in the record.
(Lee Exhibit 15 was marked for identification by Attorney Leskin.)
MS. LESKIN: And just for the record, I'm marking as Exhibit 15 an e-mail dated January 6th, 2009, from me to Neil Overholtz, Danny Becnel and Randy Hopper, copied to Judge Borg, Mr. Slonim from my office, that identifies the documents pursuant to the court order, and that includes all documents attached to or referenced in each witness's curriculum vitae, including any articles and/or presentations by the witness. So we'll make that as an exhibit.
MR. RICHARDS: That's Exhibit 14?
MS. LESKIN: That's Exhibit 15.
MR. RICHARDS: 15.
Q. And that's you giving that presentation, correct, Dr. Lee?
A. That's right, but you only showed half.
Q. But that was the entire presentation you gave, correct?

Page 97

A. Correct, but you did not show the pro --
Q. The other half is given by Dr. Sadun?
MR. BECNEL: Your Honor, that's the problem with what she's doing. She's editing and then asking questions with the witness telling her she only showed half of what was done.
MS. LESKIN: Can I ask --
JUDGE BORG: Well, she's asking specific questions. The objection is overruled. You can ask him questions when this concludes -- or she concludes.
Go ahead with your questions.
MS. LESKIN: Let me rephrase.
Q. This presentation was done in two halves, correct?
A. That's correct.
Q. And Dr. Sadun gave the first half, correct?
A. Yes.
Q. And you gave the second half, correct?
A. Yes. This was the format of the symposium section.
Q. Okay. And you gave the second half, correct?
A. That's correct.
Q. Okay. And I showed the entire presentation

Page 98

that you gave, correct?
A. But you only showed the con half.
Q. I showed the presentation that you gave, is that correct?
MR. BECNEL: Objection. She can't ask the same question after she got an answer.
JUDGE BORG: No, she didn't get an answer. The objection's overruled.
You can repeat the question, Ms. Court Reporter.
(Requested portion of record was read.)
A. That's correct.
MS. LESKIN: Okay. We need to change the tape. Let's take a break.
JUDGE BORG: Time, Mr. Videographer?
THE VIDEOGRAPHER: 3:04.
(A brief recess was taken.)
JUDGE BORG: Start time?
THE VIDEOGRAPHER: 3:10 -- or 3:11. I'm sorry.
JUDGE BORG: Okay.
THE VIDEOGRAPHER: On the record.
Q. (By Ms. Leskin) Now, Dr. Lee, referring, again, to the presentation we just watched, you went through the whole Bradford Hill criteria, right?

Page 99

A. Yes.
Q. And you stated that there's a weak but biologically plausible mechanism for NAION, right?
A. That's right.
Q. That's what you stated?
A. Yes.
Q. And you were referring to the blood pressure effect of drugs like sildenafil, correct?
A. Yes.
Q. Okay. How much does Viagra lower blood pressure?
A. Several millimeters of mercury. There was a graph on there.
Q. Let me just back up. The symposium -- The Sally Letson symposium, that's a presentation made to ophthalmic medical personnel, correct?
A. That's correct.
Q. And the people in the audience were primarily physicians, right?
A. Yes.
(Lee Exhibit 16 was marked for identification by Attorney Leskin.)
Q. And I'm go to mark as Exhibit 16 an article -- and you can give this (indicating) to counsel, please -- entitled the Sally Letson

Page 100

symposium: Neuroophthalmology update, reporting on September 14th to 16th, 2006, Ottawa, Ontario, Canada, written by you, Fiona Costello and W. Bruce Jackson, right?
A. Yes.
Q. And this is the meeting report that you prepared following the program that you co-chaired, correct?
A. That's correct.
Q. And this was published in -- What's the name of this journal? Expert Review of Ophthalmology?
A. Yes.
Q. Okay. And you wrote on the first paragraph of the article that there were six hundred and seventy-five paid attendees?
A. Yes.
Q. That it was the highest ever attendance for one of these meetings, right?
A. Yes.
Q. Now, when you said that there was a -- that the biological mechanism for NAION in ED agents was weak, that was because there are no studies showing that Viagra or any of the PDE-5 inhibitors caused a decrease in blood flow to the optic nerve,

Page 101

right?
MR. RICHARDS: Objection to form. I'm not sure what she means by studies.
JUDGE BORG: Do you understand the question?
THE WITNESS: Yes.
JUDGE BORG: Are you able to answer it?
THE WITNESS: Yes.
JUDGE BORG: Okay. Proceed.
A. The link is with hypotension, and then you have to make another link to the hypoperfusion of the optic nerve, the weakest link.
Q. Okay. Because there is no link between -- There is no link, as you just described, that's been proven by studies, correct, between the hypotension, hypoperfusion and erectile dysfunction drugs?
A. The linkage is what's weak, not the hypotension.
Q. And you mean between -- And just so I understand, what you're calling weak is the link between the drop in blood pressure and the drop in blood flow?
A. Yes. This has not been demonstrated, because we don't have good mechanisms to demonstrate this.

Page 102

Q. Have you reviewed the studies that attempt to measure blood flow following sildenafil use in the optic nerve? Strike that. Have you reviewed the studies that attempt to measure ocular blood flow following Viagra use?

A. Not Viagra use per se, but just looking at ocular blood flow, many, many papers have tried to do this. It's quite difficult.

Q. Okay. But have you reviewed any of the articles that specifically look at the effect of sildenafil or Viagra on ocular blood flow?

A. No, but that would be very hard to do, because the ocular blood flow studies in general are not that good.

Q. Let me ask you this. Are you aware of any study that demonstrates that Viagra causes a drop in blood flow to the optic nerve?

A. The weak -- The link is weak, because we cannot establish ocular blood flow in anything, let alone in erectile dysfunction agents. The study technologies for looking at ocular blood flow are not good enough to answer this question in the arteries that you're asking about.

Q. Just so I understand you, are you saying that ocular blood flow in NAION -- strike that --

Page 103

that ocular blood flow with sildenafil has not been studied?

A. No. Ocular blood flow is extremely difficult to study in the optic nerve in the blood supply that we're talking about, let alone in sildenafil. If you want to make it specific for erectile dysfunction agents, fine, but if you just say what is the status of ocular blood flow imaging right now, not good enough to answer any questions about this particular blood supply, ischemic optic neuropathy.

Q. Okay. And I appreciate the clarification that you made about this particular blood supply.

A. Yes.

Q. And my question originally was a little broader than that. Are you aware that there have been studies of ocular blood flow in other vessels following Viagra use?

A. Yes, but --

Q. And have you reviewed --

A. -- in this supply, no, because the technology isn't good enough to answer the question.

Q. Okay. I understand that. I understand what you're saying. But I want to talk about the studies looking at ocular blood flow in other vessels

Page 104

following Viagra use. Okay?

A. Yes.

Q. And have you reviewed studies looking at ocular blood flow in any vessel in the eye following Viagra use?

A. I know these exist, but I have not reviewed them carefully.

Q. And are you able to identify any study that has shown that sildenafil causes a decrease in blood flow to any vessel in the eye?

A. That's what I was alluding to when I said the link is weak in the presentation that you showed. It's not the hypotension. The hypotension part we know about, because we have measurements of blood pressure. What we don't have is the linkage to the ocular blood flow. That's where the -- The link is weak there.

Q. I just want to make sure you answered my question. Are you aware -- and that's the only question that I'm asking -- Are you aware of any study that shows a decrease of blood flow in any vessel following Viagra use?

A. No.

Q. Now, you use this term hypotension.

A. Yes.

Page 105

Q. How are you defining hypotension when you use it?

A. Hypo means low. Tension means pressure. Hypotension is low pressure. There is no standardized accepted definition of hypotension. Most people would say a 20 percent reduction in your baseline is hypotension, but it's hypotension even if it's 2 millimeters or 3 millimeters. It's, by definition, lower than your norm. But there's no standard definition for clinically significant hypotension.

Q. And that's the distinction I want to talk about -- I wanted to clarify. When you use hypotension, you're referring to any decrease in blood pressure, correct?

A. That's correct.

Q. You don't mean it to be a clinically significant decrease in blood pressure?

A. It may or may not be a clinically significant hypotension. Hypo just means it's lower, so when I say hypotension, I simply mean lower pressure.

Q. Okay. And so when you say that the erectile dysfunction drugs cause hypotension, you're simply using that to indicate that it causes a

Page 106

reduction in blood pressure?
A. Yes, and that we know is true.
Q. Okay. Are you aware of any studies that demonstrate that Viagra causes a decrease in blood flow to any part of the body?
A. This can only be inferred from the hypotension. I am not aware of any studies for specific blood flow rates to specific organs, but I would not be looking at that literature. I can only comment on the optic nerve.
Q. And when you say infer, you're hypothesizing that there is that link, but you don't have any studies that show that, correct?
A. That's correct. That is where the linkage is weak.
Q. You've used this term weak. Is there any evidence of that link between hypo -- a drop in blood pressure and the hypoperfusion you're talking about?
A. Yes.
Q. And what evidence are you referring to?
A. This is the basis of ischemic optic neuropathy. We know if the blood pressure goes too low or if the oxygenation is too low, that you'll get ischemic optic neuropathy. What we don't know is proving it with a blood flow measurement in the blood

Page 107

vessels that we're talking about, but we can see the result, ischemic optic neuropathy. So hypoperfusion is the end result after ischemic optic neuropathy. Hypotension is one of those mechanisms that we listed in the multifactorial list.
Q. But when we're referring to the erectile dysfunction drugs, the PDE-5 inhibitors, you told me that -- when you said that there was a weak link --
A. Weak link.
Q. -- you were referring to the lack of studies between showing a decrease -- a -- Strike that. You told me that the weak link you were referring to on the erectile dysfunction agents referred to the lack of studies on blood flow to the optic nerve?
A. That's correct.
Q. Do I understand that correctly?
A. That's correct.
Q. Okay.
A. We have a strong link on hypotension --
Q. Meaning a drop in blood pressure.
A. -- we have an outcome, ischemic optic neuropathy, but we do not have the middle piece, which is the blood flow, the perfusion of the optic nerve, but the limiting factor is the technology and

Page 108

the blood vessels. There's no data.
Q. Going back to your presentation, you said that the report -- in the reported cases for Viagra it's not possible to rule out chance as a cause, and that's consistent with what you wrote in your article with Dr. Newman, right?
A. Yes. Nothing in that presentation is inconsistent with what I wrote in the editorial. They're the same data.
Q. And that's because ED drugs are used in vasculopathic males, as we talked about?
A. Yes, we went over that before.
Q. You also talked -- said in your presentation -- You made reference to the weak temporal relationship between cause and effect.
A. Of the forty-three cases that were in the database.
Q. Correct.
A. Yeah.
Q. And you said that that's inconsistent with the known pharmacokinetics and the half-life, right?
A. Many of the cases reported in the database were not consistent with what we know about the onset of action of these drugs. So, for instance, if someone had their ischemic optic neuropathy a week

Page 109

later after the drug was administered, it would be hard to accept that based on the pharmacokinetics of the drug --
Q. Right.
A. -- so, in my opinion, many of those forty-three cases would have to be thrown away.
Q. And as you put up on the screen during your presentation, the half-life of the drug is four hours, right?
A. It's quite short. That's why they take it pretty close to the event.
Q. It's four hours is the half-life, right?
A. Yes --
Q. Okay.
A. -- and then there's a peak.
Q. And the peak plasma level occurs two hours after you take the drug, right?
A. Exactly. You have a very short window to get going.
Q. And you're aware that the clinical effect is greatest with the drug in that first four hours after you take it, right?
A. Yes, that's what the graph was showing.
Q. Right. Now, you said during the presentation that there was no animal model to assess

Page 110

the causal relationship, correct?
A. There is now, but at that time it wasn't ready.
Q. Okay. And what animal model are you referring to?
A. There's a rat model.
Q. Okay. And who published on that?
A. Neil Miller.
Q. And is that where they took the vessels and obliterated the vessel?
A. Yes.
Q. And is that a good animal model for an assessment of the cause of NAION?
A. No.
Q. It's an assessment for the natural progression of the disease, correct?
A. Or treatment.
Q. Okay. But you couldn't use that rat model to assess, for example, whether Viagra causes NAION?
A. No.
Q. Are you aware of any other animal model that exists that could make that assessment?
A. No.
Q. Have you reviewed any of the animal studies that were conducted during the development of Viagra?

Page 111

A. No.
Q. Since you gave your presentation are you aware of any dose response data that has been developed?
A. There's no dose response data.
Q. Now, you also said during your presentation that there's no effect specificity with regard to the NAION in the Viagra cases, right?
A. That's correct.
Q. In other words, the NAION that a patient who takes Viagra gets looks the same as any other case of NAION, right?
A. Yes.
Q. You made reference to a rechallenge case during the course of your presentation. You said there was one convincing case of rechallenge, right?
A. Yes. There are more now.
Q. Okay. But the one that you referred to was the Bollinger case report, correct?
A. Yes.
Q. That case did not involve Viagra, correct?
A. No.
Q. No, it did not?
A. No, it did not. But there are new rechallenge cases now.

Page 112

Q. What rechallenge cases -- other rechallenge cases have been published since your presentation?
A. I don't have those references. I know they exist.
Q. Okay. You're aware that we are here to take your deposition to learn the bases of your opinion?
A. Yes.
Q. And you're aware that you're required to provide us the bases of your opinion?
A. Yes.
Q. Okay. So sitting here today are you able to identify what other rechallenge cases exist?
A. No. I know they --
MR. OVERHOLTZ: I'm going to object to counsel trying to intimidate the witness to believe that he has some duty to produce documents from which he's testified he has personal knowledge.
JUDGE BORG: Do you understand the question --
THE WITNESS: Yes.
JUDGE BORG: -- Dr. Lee? Are you able to answer it?
THE WITNESS: Yes.
JUDGE BORG: The objection is overruled.

Page 113

MS. LESKIN: Your Honor, I would just indicate that the court's order limits the objecting attorneys to one attorney, and Mr. Richards is here doing a fine job. Mr. Becnel and Mr. Overholtz have all raised objections.
JUDGE BORG: What do you guys say to that?
MR. OVERHOLTZ: I think the order says two, but I'm fine to live by the rules, whatever they are.
JUDGE BORG: All right. Then we're going to have Mr. Richards make the objections.
MR. RICHARDS: Mr. Richards.
JUDGE BORG: Mr. Richards. I'm sorry. Forgive me.
A. I don't have the articles. I'm sorry. But I did not rely upon them.
Q. Okay. Now, you made reference to a case-control study during your presentation.
A. Yes.
Q. Is that Dr. McGwin's study --
A. Yes.
Q. -- Dr. McGwin and Dr. Vaphiades?
A. Yes.
Q. And the conclusion that you drew from that study is that patients taking -- patients with NAION were not more likely to report the use of erectile

Page 114

dysfunction agents in the controls, correct?
A. Yes.
Q. In other words, that study, in your opinion, did not establish an increased risk among patients taking erectile dysfunction agents, correct?
A. That's correct.
MR. RICHARDS: Objection, form.
THE WITNESS: Sorry.
JUDGE BORG: What's that? I'm sorry.
THE WITNESS: He objected.
JUDGE BORG: Yeah. Oh, I need to -- Got you. Do you understand the question, and are you able to answer it?
THE WITNESS: I do.
JUDGE BORG: It's overruled. You may answer.
A. They did not find an association.
Q. Since you gave -- I'll strike -- Let me start again. Since you published your article with Dr. Newman and since you gave this presentation at the Sally Letson symposium is there any new data regarding the association -- regarding the relationship between Viagra and NAION that you are relying on in this case?
A. Not that I'm relying upon.

Page 115

Q. I want to turn to your expert report. We've marked that as Exhibit 6 previously. Do you have that in front of you?
A. (Witness complies.) Yes, I do.
Q. Okay. Now, you gave the opinion in this report that the use of sildenafil was a significant precipitating factor for bilateral rapidly sequential NAION, right?
A. Yes.
Q. Okay. And the first key factor that you identified is the close temporal relationship between the drug ingestion and the visual loss, less than twenty-four hours, right?
A. Yes.
Q. Okay. What did -- and then -- What did you rely on to establish that there was, in fact, a close temporal relationship between Mr. Martin's ingestion of Viagra and the onset of his visual loss?
A. We only have the testimony of the patient and his medical records. That's all we have.
Q. And is that -- So what specifically did you rely upon in concluding that there was a close temporal relationship between Mr. Martin's drug use and his visual loss?
A. I believe he testified to this effect.

Page 116

Q. Are you aware of any other evidence, besides his deposition testimony, that Mr. Martin took Viagra in close temporal relationship before he experienced visual symptoms?
A. We have the medical records that are in close temporal relationship to what the patient testified. The ischemic optic neuropathy was diagnosed within the parameter -- the time parameters that he stated in his deposition.
Q. Okay. But, again, let me just be clear on what my question is. Other than the deposition testimony of Mr. Martin and his wife, what -- is there any other evidence that you're relying on that Mr. Martin took Viagra before his -- the on -- immediately before the onset of his visual symptoms?
MR. RICHARDS: Objection to form. He just testified that he relied upon the medical records in proximity to his claimed ingestion as a basis also.
JUDGE BORG: I understand the objection. Do you understand the question, Dr. Lee?
THE WITNESS: Yes.
JUDGE BORG: And are you able to answer it?
THE WITNESS: Yes.
JUDGE BORG: It's overruled.
A. The medical record and the patient's

Page 117

testimony.
Q. Okay. Show me the medical record you rely on that shows that Mr. Martin took Viagra the night before the onset of his visual symptoms.
A. We only have -- For that question we only have the patient's testimony.
Q. Okay. That's why I wanted to clarify.
A. And for the medical record it's the listing of his medicines, whether he listed -- sometimes listed and sometimes not.
Q. Okay. So the only evidence that you're relying upon that Mr. Martin took Viagra the night before the onset of his visual symptoms is his testimony and Mrs. Martin's testimony, is that correct?
A. Yes.
Q. I want you to assume for a moment that Mr. Martin did not take Viagra the night before the onset of his visual symptoms. Do you understand the assumption I'm asking you to make?
A. Yes.
Q. So if you assume that, does that change your opinion with regard to causation in this case?
MR. RICHARDS: Objection to form.
JUDGE BORG: Overruled.

Page 118

A. This is similar to what I stated in the video. If you don't have a close temporal relationship between the drug use and the event that is coherent with the pharmacokinetics of the drug, in this case we talked about the half-life and its maximum onset, so that means that night, then the case is weaker.

Q. Okay.

A. The farther away you are from the dose, the less strong the case is. So that's why in the video that you saw most of the forty-three cases I would not consider very strong for temporal relationship, because the event was not within the same day.

Q. Okay. I want to talk about Mr. Martin. So if Mr. Martin -- If you assume for purposes of my question that Mr. Martin did not take Viagra the night before the onset of his visual symptoms, does that change your opinion in this case?

A. Yes. Perhaps I didn't answer it the way you wanted me to, but, yes, it would weaken the case the further away the dose is to the event. If you say he didn't take it that night, it weakens the case, but if you say it was twenty-five hours, it's still -- it wouldn't change the opinion that much,

Page 119

but if it was two weeks before, that would change it a lot. So I guess I can't really answer it the way you're phrasing it. It's not all or none. It just weakens it or strengthens it. The closer the temporal relationship, the stronger the case; the farther, the weaker the case, but it's not all or none, because there's still drug in your system even beyond the half-life; it's just less and less and less. Like -- Am I making sense? Like if you say did he take it the night of; well, what if he had taken it the day of, still you would have an argument. But because you didn't say the night of, what does night of mean, seven o'clock, nine o'clock.

Q. Well, that's a good question. What's your understanding of when Mr. Martin says he took Viagra?

A. I think he took it the night of, and the usual way that people take this is within a few hours of wanting to use it, because it's in the instructions, so that is my impression.

Q. But I'm not talking about usually. I want to ask -- You are giving an opinion. I want to ask the basis of your opinion. So what is your understanding of when Mr. Martin took Viagra?

A. In the pre -- Sometime in the preceding twelve hours prior to the next morning, so the night

Page 120

of, so let's just say seven. I don't know. I don't know if we have the exact time or not. But, you know, the preceding day, within twenty-four hours, I think, would be my ballpark. If that's what you mean by night, yes, I think that's reasonable. I think I said that in my opinion. Less than twenty-four hours.

Q. Are you aware that Mr. Martin testified -- testified that he took it -- let's -- Strike that. You're aware there were two different incidents for Mr. Martin, correct?

A. Yes.

Q. Okay. So let's focus on the first incident. Okay?

A. (Witness nods head.)

Q. Are you aware that Mr. Martin testified that he took it between seven-thirty and 8 p.m. at night?

A. I think that's correct.

Q. Okay. How long after Mr. Martin took the the Viagra did he engage in sexual activity?

A. This we'd have to look through the record what he testified, but normally it would be within several hours of that.

Q. Do you know?

Page 121

A. No.

Q. How long after he took the Viagra did Mr. Martin go to sleep?

A. I don't know the exact time he went to sleep.

Q. What time did Mr. Martin wake up the next day?

A. I don't know the exact time.

Q. What time did Mr. Martin first notice vision loss?

A. I think it was about -- sometime when he -- after he woke up.

Q. What time --

A. I don't know the exact time of day.

Q. Do you know if it was in the morning versus the evening?

A. I think it was within the twenty-four-hour period of time. I would have to look if you want me to see what he actually said on time.

Q. Please.

A. But it's not relevant. As long as it's within the twenty-four hours, that's what would be my opinion. Twenty-four hours is reasonable.

Q. Okay. But my question is what time did he notice --

Page 122

A. I don't know any of these times.
Q. -- the onset of visual symptoms?
A. I don't know the time.
Q. Do you know what he was doing at the time he noticed the visual symptoms?
A. I don't know what he was doing.
Q. Would that be relevant to your opinion?
A. Not really.
Q. Do you know whether he noticed any visual symptoms at any other time during the day?
A. I don't know if he noticed any visual symptoms.
Q. Do you know whether he noticed any visual symptoms when he woke up that morning?
A. I don't know if he noticed visual symptoms when he woke up.
Q. Let's go to the second day -- the second eye. What time did Mr. Martin take the Viagra that night?
A. I don't know any of these time things, so you might as well not ask me those types of questions.
Q. Well, do you know how long he took it -- how long after he took Viagra that second -- before the second eye that he engaged in sexual activity?

Page 123

A. I did not precisely chart any of these time things to that level of precision.
Q. Okay. And you don't know how long after he took the Viagra he went to sleep?
A. No, I don't know any of these time things.
Q. Do you know what time he woke up?
MR. RICHARDS: Objection. He just said he doesn't know any time things. She keeps asking him time things.
JUDGE BORG: And that's overruled. She can.
A. I don't know any of these time things.
MR. RICHARDS: Even if he's already answered he doesn't know any time things?
JUDGE BORG: I understand that. You know how cross-examination works.
A. I'm sorry. I don't know any of these time things.
Q. Do you know what time he first noticed visual symptoms in his right -- in his second eye?
A. I don't know the time things.
Q. Do you know what he was doing at the time that he noticed the visual symptoms in his second eye?
A. I don't know what he was doing.

Page 124

Q. Now, as part of your review of the records in this case, did you look at the medical records from Dr. Ferrera?
A. I don't know. You'd have to let me see what you're referring to.
Q. Okay. Do you know who Dr. Ferrera is?
A. I don't know these names, unless you show me what you're looking at.
(Lee Exhibit 17 was marked for identification by Attorney Leskin.)
Q. We're going to mark as Exhibit 17 medical records that are -- that were collected from Dr. Ferrera in this litigation, and they are Bates numbered on the bottom, for the record, Martin, Ferrera 1 through 375 (indicating).
A. I doubt if I had that, because your stack is thicker than my stack (indicating).
Q. Okay. You'll notice that on the bottom right-hand corners are numbers, correct?
A. Yes.
Q. Okay. And those are Bates numbers that were put on the records by my office when we received them from Dr. Ferrera, and they're really there to help ease reference to various documents. Okay?
A. Yes.

Page 125

Q. Now, if you look at page 114 of Dr. Ferrera's records --
A. (Witness complies.) Yes.
Q. -- those are records from May 1st, correct?
A. Yes.
Q. Do you see on the bottom of that page there's a record from May 1st?
A. I see --
MR. RICHARDS: Objection to form. He can read what's on here for May 1st. He didn't create the records. He didn't know if it was actually on May 1st or not.
JUDGE BORG: Do you --
MS. LESKIN: I'll rephrase.
JUDGE BORG: All right.
Q. I'm directing your attention to the bottom of page 114 of Dr. Ferrera's records. Are you there?
A. Yes.
Q. Okay. And you'll see on the bottom of that page there is a record dated May 1st, 2002, correct?
A. Yes.
Q. Did you see this record before?
A. I think I have seen it, yes.
Q. Okay. So this (indicating) is in the records that plaintiff's counsel provided to you?

Page 126

A. I have this page right here (indicating).
Q. Okay. And you've marked it with a Post-it note?
A. Yes.
Q. Okay. Did you mark that Post-it note, or did plaintiff's counsel mark that for you?
A. I marked it.
Q. And you marked it, because that's the day that Mr. Martin first reported his vision loss, right?
A. Yes.
Q. On May 1st, 2002, do you see any record -- and you feel free to look back and forth in Dr. Ferrera's records, but on May 1st, 2002, do you see any indication that Mr. Martin reported to Dr. Ferrera that he had taken Viagra the night before he noticed his vision loss?
A. Well, there are no medicines, so --
Q. I'm sorry?
A. There are no medicines.
Q. So you do not see anything that refers to the use of Viagra the night before, is that correct?
A. Yes, because there are no medicines listed, unless there's some other part of this record. No. The answer to your question is no. No medicines are

Page 127

listed.
(Lee Exhibit 18 was marked for identification by Attorney Leskin.)
Q. I'm going to mark as Exhibit 18 (indicating) medical records that we received from Dr. Nichols, and they are Bate stamped Martin, Nichols 1 through Martin, Nichols 28.
A. Are you done with this one (indicating)?
Q. For now. You can put that off to the side, but don't get rid of it.
A. (Witness complies.)
Q. Have you seen these records before, Doctor?
A. Yes, I think I have some of these.
Q. Okay. If you'd look at Nichols 10.
A. (Witness complies.) Yes.
Q. Have you seen this page before?
A. I think so. Anyway, yes, I think so.
Q. Okay. And do you understand that to be an intake form that was completed by Mr. Martin or his wife the first time they saw Dr. Nichols?
A. Yes.
Q. And that's dated May 1st, 2002, correct?
A. Yes.
Q. And you'll see that there's a question 8 that says do you take any medications, correct?

Page 128

A. Yes.
Q. And what medications did Mr. Martin list on this form?
A. Catapres.
Q. Any others?
A. No.
Q. And I'll ask you to turn back in those records to Nichols 3.
A. (Witness complies.)
Q. Are you there?
A. Yes.
Q. Have you seen this record before?
A. Yes, I think so.
Q. And you'll see on the bottom half of that page there's a record dated May 1st, 2002, correct? Are you with me?
A. Yes.
Q. And you'll see there's a note on the chart that says Catapres?
A. Yes.
Q. Do you see anywhere on this form where Dr. Nichols indicated that Mr. Martin took Viagra the night before the onset of his eye condition?
A. No, but he didn't really ask that either.
Q. Well, did you review Dr. Nichols'

Page 129

deposition transcript in this case?
A. No.
Q. Are you aware that Dr. Nichols gave the following testimony: Question -- and this is, for the record, page 15, lines 12 through 24, of Dr. Nichols' deposition testimony -- question, under number 8 it asks for any medication the patient is taking, and Mr. Martin mentioned Catapres? Answer, correct. Question, did you review that information with Mr. Martin at the time you saw him? Answer, yes. Question, and were there any other medications that Mr. Martin identified for you as of May 1st, 2002? Answer, no. Question, if Mr. Martin had told you as of May 1st, 2002, that he had taken any other medications, would you have noted that in his chart? Answer, yes, I would have. You'd not seen that testimony before?
A. No, but it doesn't say he asked about Viagra there either. If you don't ask, men will not disclose this information.
Q. I'm going to ask you to turn back to Dr. Ferrera's records and ask you to turn to Ferrera page 92.
A. (Witness complies.) Yes.
Q. Are you on that page?

Page 130

A. **Yes.**
Q. And if you look at the entry on the bottom of that page, you'll see it's dated October 6th, 2004?
A. **Yes.**
Q. If you look at the fourth sentence of that entry, it says, quote, he still has erectile dysfunction but relates to me that he does not feel that the Viagra was given at the time that he went blind, end quote. Do you see that sentence?
A. **Yes.**
Q. Had you seen this entry before today?
A. **I think I have seen this.**
Q. Do you know who Dr. McEllistrem is?
A. **No.**
Q. Let me hand you an excerpt from Dr. McEllistrem's records.
(Lee Exhibit 19 was marked for identification by Attorney Leskin.)
Q. Well, you know what, I'll mark Dr. McEllistrem's records as Exhibit 19 (indicating), and these are Bate stamped Martin, McEllistrem 1 through Martin, McEllistrem 40, and I'll ask you to take a look at that and tell me whether you've seen these records before.

Page 131

A. **(Witness complies.) I don't think I have seen this.**
Q. If you take a look at page 31 of Dr. McEllistrem's records.
A. **(Witness complies.)**
Q. And you see that's an entry dated at the top October 29th, 2002?
A. **Yes.**
Q. Do you see that?
A. **Yes.**
Q. And that's about seven months after Mr. Martin's onset, correct, of his vision loss?
A. **Yes.**
Q. And you'll see that Dr. McEllistrem wrote patient had new medication for HTN -- That's hypertension, right?
A. **Yes.**
Q. -- which caused him some dizziness on standing up from squatting position, and he suddenly developed difficulty with vision and was felt to have had vascular occlusion to optic nerves. Did you see that at the time?
A. **Yes.**
Q. Did you see this entry before today?
A. **I think I have seen this entry.**

Page 132

Q. Did you, in fact, see this before today?
A. **I think so.**
Q. Okay. If Mr. Martin -- I want to go back to Dr. Ferrera's record from October 6th, 2004, the one we referenced earlier --
A. **Can you tell me that number again?**
Q. Sure. It's Ferrera 92.
A. **(Witness complies.) Okay.**
Q. -- where Dr. Ferrera wrote he still has erectile dysfunction but relates to me that he does not feel that the Viagra was given at the time he went blind.
A. **Yes.**
Q. If Mr. Martin's statement to Dr. Ferrera that he was not taking Viagra at the time of the NAION onset, if that statement is correct, does that change your opinion as expressed in your report?
A. **Yeah, if he didn't take it, then it's hard to establish close temporal relationship.**
Q. The second element that you identified -- key factor you identified in your report is the nocturnal use of the agent in question.
A. **Yes.**
Q. What is the significance of the nocturnal use?

Page 133

A. **One of the things that people believe is that nocturnal hypotension is a predisposing or precipitating factor in ischemic optic neuropathy, so if you take the agent during the day, it might not cause your blood pressure to go down as much as if you take it at night.**
Q. Now, according to Dr. Heyreh's nocturnal hypotension theory, the patient notices the vision loss upon awakening, correct?
A. **They can notice it upon awakening, but they can notice it at any time.**
Q. Okay. Are aware that Dr. Heyreh has written that one of the bases to support his nocturnal hypotension theory is that the patients awake with vision loss?
A. **Yes.**
Q. The next key factor you wrote -- Well, strike that. What was Mr. Martin's blood pressure before he went to bed?
A. **I don't know.**
Q. How far did his blood pressure drop overnight?
A. **I don't know.**
Q. What was his blood pressure when he woke up in the morning?

Page 134

A. I don't know.
Q. What was his blood pressure immediately before the onset of his eye loss -- vision loss?
A. I don't know. I don't know any of these blood pressure things, because they weren't recorded.
Q. So you don't, in fact, know whether or not Mr. Martin suffered from nocturnal hypotension, is that correct?
A. On the nights in question?
Q. Correct.
A. Yeah, we don't know that.
Q. The next key factor you wrote is the bilateral and rapidly sequential nature of the NAION in close proximity in time to one another, right?
A. Yes.
Q. And as we identified earlier in Dr. Newman's report on the decompression trial, the median interval was 1.2 years, right, that she reported between eyes, correct?
A. That's correct.
Q. But the range was between sixteen days and six years, correct?
A. That's correct.
Q. Number 4 you wrote, was a biologically plausible mechanism for the effect. Is that the same

Page 135

effect that we've been talking about earlier?
A. Hypotension is the biologically plausible --
Q. Okay. And that's the same effect that you described on the video as weak, correct?
A. No, the hypotension is not weak. The hypotension is strong. The weak link is the hypoperfusion of the optic nerve head, which we do not have that.
Q. Okay. How far did Mr. Martin's blood pressure drop as a result of taking Viagra?
A. We don't know that.
Q. How far does your blood pressure have to drop in order to cause NAION?
A. We don't know that, because there are predisposing factors, and there are precipitating factors. The predisposing factors are the things we talked about before.
Q. The vasculopathic risk factors?
A. Vasculopathic. And so someone who's totally healthy and has good blood vessels might be able to sustain a significant hypotension, and nothing would happen to them, but someone who has predisposing factors, a little bit of hypotension may be enough to precipitate an event.

Page 136

Q. Okay. So someone with predisposing risk factors, how far does their blood pressure have to drop in order to cause NAION?
A. We don't know that.
Q. How long does their blood pressure have to be dropped in order for there to be NAION?
A. We don't know that.
Q. How long has Mr. Martin's blood pressure dropped, if at all?
A. We don't know any of the blood pressure questions that you're asking me, because there are no blood pressure measurements for the nights in question.
Q. The next point you raise is the lack of alternative etiologies for the effect. Now, you identified exclusion of temporal arteritis here. That's simply ruling out another cause of the effect, the loss of vision, correct?
A. No, there are two types of ischemic optic neuropathy. Remember we talked about arteritic and nonarteritic?
Q. Right.
A. Arteritic is what you would be worried about if you have bilateral and rapidly sequential. So if someone has both eyes that close together, we

Page 137

really are worried about temporal arteritis, but it was not the case.
Q. So for number 5 the only thing you're referring to is whether he had nonarteritic as opposed to arteritic, correct?
A. Well, there are other causes of optic neuropathy, inflammation, infection and all these other things --
Q. Okay.
A. -- but none of them were present either, but I gave the example of temporal arteritis.
Q. Okay. So when you -- On number 5 when you say the lack of alternative etiologies for the effect, are you referring solely to the diagnosis of NAION as opposed to other disease conditions?
A. Yes.
Q. Okay.
A. So --
Q. You're not referring to other potential causes of NAION here in this sentence?
A. Both.
Q. Okay.
A. There was no other precipitating factor that could be implicated, even though there were a number of predisposing, so -- For example, if you

Page 138

have surgery or blood loss, you can get ischemic optic neuropathy. He had no -- nothing else to blame, so it's either coincidence, or it's the drug. Those are your two choices.

Q. Okay. How do you rule out coincidence in this case?

A. You cannot. Those are the two competing hypotheses --

Q. Okay. And --

A. -- coincidence or not.

Q. Okay. And you cannot rule out coincidence in this case, is that true?

A. You cannot rule out coincidence.

Q. Mr. Martin told his -- told Dr. McEllistrem that he had taken Catapres -- just started taking Catapres, correct?

A. Yes.

Q. Could Catapres be a precipitating factor for NAION?

A. Yeah.

MR. RICHARDS: Objection, form.

A. Yes.

MR. RICHARDS: She hasn't established he even knows what Catapres is.

JUDGE BORG: The witness answered the

Page 139

question, so --

THE WITNESS: Sorry. I'm too fast on the draw.

Q. I'll back up. Do you know what Catapres is, Doctor?

A. I know what Catapres is.

Q. What is Catapres?

A. Antihypertensive drug.

Q. Could Catapres be a precipitating risk factor for NAION?

A. Yes.

Q. How are you able to rule out Catapres? Well, strike that. Are you able to rule out Catapres as a potential precipitating cause in this case?

A. You cannot rule this out. You would apply the same criteria, when did you take the drug, what was the half-life and maximum onset, so if you say, look, I took the Catapres, then that night I went to bed, when I woke up I lost my vision, and every time I take the Catapres I get dizzy, whatever, then these are things that would suggest an alternative etiology, but there's no test to rule out Catapres.

Q. So have you ruled out Catapres as a potential cause for Mr. Martin's NAION?

A. There's no test to rule it out.

Page 140

Q. So you have not ruled out Catapres, is that right?

A. I have not, and there is no test to do that. There is no -- You can only apply the criteria, again, do the same things, same list, same seven things, so -- It's weaker on Catapres if you apply the seven criteria of Austin Bradford Hill.

Q. Okay. The last key factor you identified is the apparent rechallenge with the same effect, and you're referring to the one eye and then the second eye, that Mr. Martin testified he took Viagra the night before?

A. We skipped number six, but maybe --

Q. Oh, I'm sorry. You're right. I did. Number 6, the presence of predisposing vasculopathic risk factors. Now, you told me, though, that those factors in and of themselves are risk factors for NAION, correct?

A. That's correct. So --

Q. And a patient could have those vasculopathic risk factors and nothing else and still get NAION, correct?

A. That's correct.

Q. And that's why you're not able to rule out coincidence?

Page 141

A. That's correct, too.

Q. Okay.

A. But they're important in establishing the predisposition. So the predisposition is probably necessary for a precipitating effect to occur if there's some predisposing thing. Like I said before, if you're totally healthy, and your blood pressure goes down 4 millimeters, probably nothing will happen to you.

Q. If Mr. Martin had walked into your office with the same predisposing vasculopathic risk factors that you reference here but had not taken Viagra, what would you say caused his NAION?

A. Then we would be going through the other list of things, including the Catapres and the -- Other things would be subjected to the same Austin Bradford Hill criteria.

Q. And all of those things still are on the differential for Mr. Martin, correct?

A. That's correct.

Q. And as you said, you cannot rule out coincidence, and you cannot rule out Catapres, correct?

A. There's no test to rule these things out.

MS. LESKIN: I'm told we have to change the

Page 142

tape, so -- I need more than three minutes for my line of questioning, so let's take a break.
JUDGE BORG: Time?
THE VIDEOGRAPHER: 4:07.
(A brief recess was taken.)
JUDGE BORG: We're on. Time?
THE VIDEOGRAPHER: 4:17.
JUDGE BORG: 4:17. Ms. Leskin, go ahead.
Q. (By Ms. Leskin) Okay. Doctor, the last key factor you identified in your report talks about the apparent rechallenge in this case?
A. Yes.
Q. Okay. Now, a rechallenge -- Let's go through some definitions. A rechallenge -- A challenge is when you give someone a medication, correct --
A. Yes.
Q. -- in the context of a medication, right?
A. (Witness nods head.)
Q. A challenge is you give someone the medication, correct?
A. Yes.
Q. A positive challenge is they have an effect from the medication, correct?
A. Yes.

Page 143

Q. And a negative challenge is they have no side effect -- they have no effect from the medication?
A. Yes.
Q. Okay. And a dechallenge is when you take the medication away, they get -- You take the medication away, that's dechallenge, correct?
A. Yes.
Q. And a positive dechallenge is you take the medication away, and they get better, right?
A. Yes.
Q. And a negative dechallenge is you take the medication away, and they either have no change, or they get worse --
A. Yes.
Q. -- right?
A. (Witness nods head.)
Q. And a rechallenge is when you give someone else -- when you give them the medication again -- the same person the medication again, correct?
A. Yes.
Q. And a positive rechallenge is when you give the patient the medication again, and they have an effect again, correct?
A. Yes.

Page 144

Q. And a negative rechallenge is when you give someone a medication again, and they don't have an effect again, correct?
A. Yes.
Q. Okay. Were you aware that Mr. Martin started taking Viagra in April of 1998?
A. Yes.
Q. And he took it once or twice a week, correct?
A. Yes.
Q. So by the time that he had his NAION in his first eye, the end of April 2002, would you agree with me that he would have used Viagra approximately two hundred times?
A. Yes.
Q. And he had no side effects from any of those, correct?
MR. RICHARDS: Objection to form.
A. He did not have ischemic optic neuropathy.
Q. Correct. Thank you. Thank you for clarifying that. He had no ischemic optic neuropathy after taking Viagra, correct, on those first two hundred times?
A. On those previous challenges.
Q. Okay.

Page 145

JUDGE BORG: I was going to sustain that objection.
MR. RICHARDS: You were?
JUDGE BORG: Yep.
MR. RICHARDS: It would have been the first.
JUDGE BORG: But Dr. Lee straightened Ms. Leskin out.
Q. We are right on track with each other. So under the definitions we just went over, each time that Mr. Martin took Viagra, that's a rechallenge, correct?
A. Yes.
Q. And so Mr. Martin was, in fact, rechallenged two hundred times with Viagra without getting ischemic optic neuropathy, is that correct?
A. Yes.
Q. You told me earlier -- We talked about Richard Stanley. Do you remember that --
A. Yes.
Q. -- way back at the beginning of the deposition?
A. (Witness nods head.)
Q. And you told me that your opinion on Mr. Stanley was not as strong, correct?

Page 146

A. Yes.
Q. Why was Mr. Stanley's case not as strong?
A. I don't remember exactly the circumstances, but I believe that he did not have the full seven criteria. He only had three or four. I can't remember exactly.
MS. LESKIN: I have nothing further.
JUDGE BORG: Mr. Richards, are you going to do it?
MR. RICHARDS: I'm going to take a short break --
JUDGE BORG: Okay.
MR. RICHARDS: -- and get my questions together and --
JUDGE BORG: All right. We can do that.
MS. LESKIN: Okay.
JUDGE BORG: Off the record at --
THE VIDEOGRAPHER: 4:20.
(A brief recess was taken.)
JUDGE BORG: Back on at --
THE VIDEOGRAPHER: 4:32.
JUDGE BORG: 4:32. Go ahead.
CROSS-EXAMINATION
BY MR. RICHARDS:
Q. Good afternoon, Dr. Lee. I'm going to

Page 147

follow up with some questions that Ms. Leskin touched upon, and I may want to -- can you --
MR. RICHARDS: Can the videographer see Dr. Lee okay?
THE VIDEOGRAPHER: Yes.
MR. RICHARDS: Okay.
Q. I know I'm sitting beside you, so I apologize if it seems a little strange, but -- you had testified earlier that back in -- your current practice, about two hundred or three hundred NAION cases -- You see about two hundred or three hundred NAION cases a year, is that right?
A. Yes.
Q. And with any of those two or three hundred NAION cases that you see a year, are you aware or do you recall as to whether or not any of those took -- any of those patients took a PDE-5 inhibitor within a temporal relationship to developing the onset of this disease?
MS. LESKIN: Objection to the extent that it violates patient privacy, people who are not patients -- plaintiffs in this litigation.
JUDGE BORG: Overruled. I'm going to overrule that.
Q. And I don't want you to name any patient

Page 148

names, but if you can just tell me generally.
A. We always ask all our patients who have NAION if they have taken Viagra or any of the erectile dysfunction agents.
Q. And why do you ask that question?
A. Because of the question of causality, and also we apply the Austin Bradford Hill criteria to their individual cases so that we can advise them appropriately on the risk and benefit of using these agents.
Q. When did you -- If you recall, when did you start asking that question?
A. Right when it all started coming out in the lay press, that would be in the mid 2000s, very close in time to the FDA warning that was listed as an exhibit. I can't remember which one it was.
Q. So you apply the Bradford Hill criteria for each patient that you see that informs you that they took Viagra or a PDE-5 inhibitor?
A. Yes, and we have to make a special effort to ask them about it, because, as I alluded to before, many patients do not disclose that they are taking these agents for various stigma reasons, they're embarrassed by it, so if you don't ask, they definitely don't tell you.

Page 149

Q. And in 2002 prior to the time that lay opinion became -- the lay press kind of picked up on the possible association there was even less of a reason for a patient to inform a doctor that they may have taken Viagra?
MS. LESKIN: Objection, calls for speculation.
JUDGE BORG: Overruled.
A. Yes, patients were not aware of this until it reached the lay press level and made all the headlines, et cetera.
Q. In fact, physicians were generally not aware of it before it reached the lay press and made the headlines, right?
MS. LESKIN: Objection, calls for speculation.
A. Yes, that --
JUDGE BORG: I'll overrule --
MS. LESKIN: If he's providing an expert opinion on that, Judge, then he needs to have a basis for that. That's not in his report.
JUDGE BORG: A little more foundation would make it a little easier with respect to the objection.
Q. In two thousand -- Prior to 2005 did you

Page 150

have a reason to believe that Viagra or any PDE-5 inhibitor was associated with NAION?

A. No, only after that did it become a big issue and become part of our standard questionnaire.

Q. So in applying the Bradford Hill criteria to the patients that you had mentioned, the two or three hundred, do you recall whether or not you had made any causal assessments on any of those patients?

MS. LESKIN: Objection. Those patients are not plaintiffs in this litigation. He is not being offered as an expert in those. To the extent they form the basis for his opinion, then he needs to be --

JUDGE BORG: So is your objection to form?

MS. LESKIN: Yes.

JUDGE BORG: It's overruled.

You can repeat the question.

MR. RICHARDS: Madam Court Reporter, could you read the question?

MS. LESKIN: And to the extent it's not an objection to form, we reserve the right to raise it as to admissibility with the court.

JUDGE BORG: Of course you do.

MS. LESKIN: Just making clear.

JUDGE BORG: That goes without saying.

Page 151

All of those objections are reserved pursuant to the court's order.

(Requested portion of record was read.)

A. Yes, so if they have a weak assessment, as I mentioned in the presentation, we tell them the risk is low; if it's moderate, then we tell them the risk is moderate; if it's high, and they have all seven criteria, I tell them the risk is high, and they have a quality of life decision whether they want to continue to use the agent.

Q. Ms. Leskin also asked you about the Pfizer study that the institution here at the University of Iowa is undertaking. You had mentioned that you doubted whether your university would engage in that study, that there were some questions regarding the -- I guess the protocol. Could you elaborate on what questions that you had or some of your colleagues may have had regarding the protocol posed by Pfizer?

A. There have been numerous questions raised about this study, and the major ones are sample size. Because nonarteritic ischemic optic neuropathy is so uncommon, it would take many, many thousands of patients scattered over many, many centers, and you would probably have to follow them for a significant

Page 152

number of years to establish a cause and effect relationship, which, I believe, is why the FDA is trying to do this. It's not going to be able to be done by one single center, so -- it's going to take a lot of patients and a lot of time, but if the study is too small or too short, then it will show the opposite effect; it will show there is no causal relationship, even though there could be if you had more patients and a longer time.

So I think the major quibbles with the study are it needs to be bigger and needs to have longer duration of follow-up, and then there were some side disagreements about collecting other additional data that might be useful. Since we're getting the information on ischemic optic neuropathy anyway, we might as well collect a whole broad range of data points to learn something about the disease, but the company is not willing to do this.

Q. Is there a difference between a cause and effect relationship in the scientific community versus a cause and effect relationship in the legal community?

A. Yes. My understanding of it is that when we're trying to establish cause and effect for a population, that's an epidemiologic type of study

Page 153

that's going to require many, many, many patients followed over years and in medical centers. That's the whole point of the prospective studies that have been mandated by the FDA for the companies. But when we're talking about an individual patient that's sitting there in the room with you, you can only advise them on their specific situation, their predisposing risk factors, and then we apply the Austin Bradford Hill criteria to give them the best advice that we can based on their specific situation. So in a legal setting I was asked to comment about Mr. Martin, and that's what I have done here.

Q. And the legal setting is not to a 100 percent certainty, right?

A. No. I was only asked is it more likely than not, and that's why some of the cases that they presented I didn't feel were very strong; some I thought were very strong. Just as I presented in the -- much more forcefully in the presentation that was shown, a lot of the cases in the FDA database are weak, but some, like Mr. Martin's, are very strong.

Q. When you advise patients regarding various risk factors associated with ED drugs, what do you advise them?

A. We try to tell them their risk. I try to

Page 154

establish the Bradford Hill criteria. The most important is the temporal relationship coherent with the pharmacokinetics of the drug. That's the thing we talked about before. So if they have their ischemic optic neuropathy, and it was like a week later, I think the risk is not so good, but if someone has had ischemic optic neuropathy, and then they got a rechallenge, and they got it again, boy, that's really going to make us nervous, and we're going to tell that person there's a significant risk for getting it again, and we probably would recommend not using it. So there's -- A risk/benefit decision has to be made based on the individual patient and provide a discussion about the Bradford Hill criteria, and then we lay out the risk/benefits to them. I don't tell them they can't take it, because it's a life-style choice, but I tell them the risk is high, medium or low.

Q. On direct examination you had talked about comparing the two groups in Dr. Newman's study and how you can't provide -- I think comparing the two groups does not provide you with an incidence rate. Could you elaborate on that, why it's improper to compare what you called apples and oranges in Dr. Newman's study?

Page 155

A. Because counsel was trying to lump in the bilateral cases with the bilateral sequential cases. The bilateral sequential cases tell you the incidence of fellow eye involvement, and that number is 14.7 percent. The number we tell patients is between 12 and 14 percent to give it some range, because that number is not hard and fast. But the patients that came already to the study with bilateral, they cannot be included, because they already had their event before, and so you don't know when that occurred, whether it was last year or five years ago to ten years ago, and someone who's already had ischemic optic neuropathy in one eye is a lot more likely to go to the doctor, because they already have it in the one eye, so you cannot use them for anything, so --

It's interesting that they were bilateral, but it cannot be used to establish the incidence rate in the fellow eye because of ascertainment bias, which is what we talked about before. Ascertainment bias means you're already collecting a bunch of people who are bilateral, because those are the ones that are super likely to go to the doctor and end up at a medical center where a study is being done, so that's ascertainment bias. So we cannot include the bilateral patients who already had it in one eye as a

Page 156

bilateral for the incidence calculation, because they're the ones that are going to go to the doctor. The only thing we include, the 14.7 percent fellow eye involvement that occurred over the five-year period of the study. I did not make this clear, I don't think, to counsel very well, but it's apples and oranges.

Q. Since you've published your paper -- your Viagra paper -- or your PDE-5 inhibitor paper in 2005 -- in October 2005 are you aware of whether Pfizer has undertaken any prospective or case-control studies to determine a cause and effect relationship?

A. Yes, I think they have been mandated by the FDA to do this and to try and get at this, and that's where we are looking at the preliminaries, and I attended the preliminary meeting, but I don't have any involvement with it anymore because of moving to Houston.

Q. So between October 2005 and until relatively recently, you mean -- how many months ago?

A. In the last year.

Q. Okay. And between October 2005 when you published your study and last year you're not aware of any studies -- prospective case-control studies that Pfizer has undertaken?

Page 157

A. No, but why would they want to do this? I mean, that's why it has to be mandated.

Q. What do you mean by that?

A. If there's a possibility that your drug could cause blindness, you don't want to find that out, let alone pay for it, but if FDA mandates it, then you have to do it.

Q. And your understanding is the FDA has mandated that they undertake these studies?

A. Yes, and I think that's a good thing, because that's the only way we're really going to be able to answer the question.

Q. And that's the ultimate goal, really, isn't it, is to try to find out whether, in fact, there is a cause and effect relationship with this drug and NAION, right?

A. That's correct, that's the only way to know. The only way to know is to have a prospective observational study where we can look at specific time points, capture all the patients and see whether it really is cause and effect or whether it's coincidence.

Q. You had made reference to the fact that there may be more cases -- there may have been more cases published since the 2005 FDA alert. Are you

Page 158

referring to any specific cases or just generally?
A. We know that many more cases have been published in the literature and also that the database has more patients in it. I have not accessed this database lately, but there are definitely more patients in there from what people are saying. I think it's in the fifty range, but I don't know. There's definitely more patients.
Q. In the presentation that was played on the TV you said that the presentation that was shown to you, the seven and a half minutes, did not show the pro side of causation. It showed, I guess, your con side of causation. Who did the pro side of causation?
A. Alfredo Sadun. That's why it's misleading to just show the con side, because the whole point of the presentation was one doctor took the pro side, and the other doctor took the con side. We would never present like that if I was just giving the presentation about erectile dysfunction agents, because I would never leave off just the pro side. That would be ridiculous. The whole point of that presentation was to have two doctors to show the pro and the con. If you only show the con, that is completely misleading and -- I still stand by

Page 159

everything that was said in that presentation, because it totally jibes with my opinion. There are medium, weak and strong cases. Mr. Martin's case happens to be a strong case. If you notice, the Austin Bradford Hill criteria are -- The exact same criteria that we are using to support Mr. Martin's allegations are the same things I mentioned in the presentation. But it's misleading to not show the pro side.
Q. Do you recall what the pro side was?
A. Yes, the pro side was the same points on the Austin Bradford Hill except the other guy said the opposite of what I said, so --
Q. Why were you tasked to take the con side?
A. It was just luck of the draw. I mean, you have to take the pro and the con. I took the con side, because at that time it was -- you know, the data was equal, that there could be -- It was a controversial topic. It's still a controversial topic. So I think that what they neglected to include in there was -- The title of the whole symposium was controversies in neuroophthalmology; not that there was a right answer and a wrong answer, but that there was a pro position and a con position, and each doctor was assigned to take one side or the

Page 160

other. I happened to draw the con side. But it's totally misleading to just show the con side.
Q. So in applying -- in rendering your opinion in this case you applied the Bradford Hill criteria to Mr. Martin's case?
A. Yes. In fact, I think that's why you chose me to be an expert. You knew that this was my opinion. You had my published editorial. Everything that was brought up in this deposition is my opinion. I don't run away from it. I stand by every single thing that we've said. The whole point is I am a skeptic and have been a skeptic the whole time, but for this particular case, this patient's case meets the more likely than not standard for causality, the legal thing we're talking about. Does it prove for all the patients that erectile dysfunction agents cause nonarteritic anterior ischemic optic neuropathy; no, but no single case can prove that. That means an observational prospective study. But if you're just asking me about this patient, yes, it is my opinion that more likely than not it was a precipitating factor.
Q. And by "precipitating factor," explain to me what you mean by that.
A. So we talked a little before about what

Page 161

causes ischemic optic neuropathy. Predisposing factors and precipitating factors. Predisposing factors are all the things that were vasculopathic that were mentioned, high blood pressure, diabetes, cholesterol, smoking, age. Those are all predisposing factors. A precipitating factor is nocturnal hypotension. Nocturnal hypotension that is made worse by using a medicine that lowers your blood pressure like an erectile dysfunction agent is a precipitating factor. So you have to have the predisposing factors, they push you to some threshold, and then something is the straw that breaks the camel's back and pushes you over the edge. In my opinion the erectile dysfunction agent in this case is the most plausible precipitating factor in someone who is predisposed to the development of nonarteritic anterior ischemic optic neuropathy.
Q. But Pfizer points out that he had taken it -- Mr. Martin had taken it approximately two hundred times before, so explain that -- explain -- explain that to me.
A. Well, it's a threshold effect. It's not really a toxicity of the medicine, which I made a lot of -- spent a lot of time in the presentation discussing the difference between toxicity, which

Page 162

this doesn't look anything like toxicity, so it's not that the erectile dysfunction agent produces toxicity --

THE WITNESS: Is he saying something?

MR. RICHARDS: Hey, Neil?

MS. LESKIN: Neil?

MR. RICHARDS: Neil?

A. Keep going?

Q. Yes.

A. It's not a toxicity. It's a side effect with a biologically plausible mechanism. So if you don't reach the threshold, your blood pressure isn't low enough, you won't get the event, so it's kind of an all or none effect; you either get ischemic optic neuropathy or you don't. The fact that you did not get it two hundred times before is not the same as a normal rechallenge for toxicity. In a normal rechallenge for toxicity, like I get a rash every time I take this medicine; every time you take it, we rechallenge you, you get the rash, that's a legitimate rechallenge, and then for that you would say, look, you were rechallenged two hundred times, you didn't get it.

In an all or none effect you don't get it over and over again; it's either all or none.

Page 163

So you can take it two hundred times and never get the threshold, but then you take it the two hundred and first time, and that is the thing that pushes you over the edge. So the fact that there were two hundred other dosings is not the same as what we use for rechallenge for side effects like rash or nausea, whatever. It's not the same, because it's an all and none effect. In this case NAION is an all or none threshold effect.

Q. There were some questions raised about whether or not Mr. Martin may have taken the drug within twenty-four hours. Your opinion is based upon the fact -- the assumption that it is true that Mr. Martin took the drug within approximately twenty-four hours of developing NAION, correct?

A. Yes.

Q. Okay. You're familiar with Catapres -- the drug Catapres?

A. Yes.

Q. Are you aware whether or not Catapres has anything in its packaging or labeling regarding AION, ION or NAION?

A. It doesn't have that.

Q. Are you familiar with whether or not Mr. Martin was taking Zocor?

Page 164

A. Yes.

Q. Are you aware whether or not Zocor has anything in its packaging or labeling regarding ION, AION or NAION?

A. It doesn't.

Q. Only Viagra has the warning regarding NAION, right?

A. I think the other erectile dysfunction agents also have similar things in --

Q. So it's classified?

A. Classified, yeah. In fact, if we had shown the pro side, that was what was argued. Every single point that I argued with the Bradford Hill criteria was argued on the other side by my esteemed opponent, so -- You know, when you're on the con side, you don't mention things that he just said, that would be redundant, plus it's not the point of the symposium, so --

Q. What was the point of the symposium?

A. To demonstrate that there are two sides to every issue, a pro and a con; it was a controversy then, and it's still a controversy now, and that you could use the Austin Bradford Hill criteria for the exact same set of patients and come to different conclusions. And the conclusion that I drew, and I

Page 165

try to impress upon all of our residents and medical students and everyone we talk to about this issue, is you must apply them on individual patients, because we don't have epidemiologic data to say one way or the other, so we have to just use what we have on individual patients to make the decision.

Q. I want to get into the blood flow studies that Ms. Leskin had mentioned or the lack of blood flow studies. I want to zero in on the fact that -- is it true that there are no -- there are no scientific -- there's no scientific means to study the blood flow at the point where NAION is alleged to occur?

A. That's correct. That's why it's not really legitimate. It's somewhat misleading to say there are no studies to look at the blood flow of this for Viagra, because there are no studies to look at the blood flow in that particular area for anything. So that's misleading to say that there are no studies for this erectile dysfunction agent for ocular blood flow for AION, because there are no good studies for this for anything, so it's true, but it's not relevant.

Q. Is it your understanding that blood flow to the optic nerve head and blood flow to the other

Page 166

parts of the body are the same, or are they different?

A. It's different, so -- There are clearly susceptibilities of the optic nerve head that are different than other parts of the body, mostly because there are not redundant systems; the perfusion is kind of far from the heart, it's the last place to go. So there are all sorts of -- a number of hypotheses why ischemic optic neuropathy occurs, and you don't get the stroke at the same time in your brain, so it seems to be just isolated to your optic nerve.

Q. In your paper from 2005 you had mentioned some of Pfizer's clinical studies; in fact, there were more than thirteen thousand patients, and there were no reported cases of NAION in these patients. Do you know whether or not thirteen thousand patients is thirteen thousand patients measured in terms of patient years? Do you understand what I'm asking?

A. Yes.

Q. Do you know the difference between patient years versus individual doses?

A. Yeah. I don't know which number that number refers to in terms of patient years or actual patients and how long they were followed for, so --

Page 167

if you follow for too short a time, you won't -- thirteen thousand would be a small number; it's not sufficient time to develop ischemic optic neuropathy given the incidence numbers that we know about.

Q. Is it fair to -- What do you consider to be an appropriate dose response time period? If someone took it once in a month, is it appropriate to calculate them as having -- Strike that. I don't want to confuse the issue. You mentioned in your paper the Johnson and Arnold study and another study measuring the estimated incidence rate for folks with NAION per one hundred thousand. That's the Johnson and Arnold. Are you aware of any other -- What is your understanding of the incidence rate in the general population between -- for NAION? Is it just Johnson and Arnold, or is it --

A. The Mayo Clinic is also another one that's frequently quoted, so it's somewhere in that range.

Q. And it's your understanding it's still in the range of 2.3, according to Johnson and Arnold, versus the 10.3 at Mayo Clinic?

A. Yeah, it's somewhere in that range. It's low. So that's why it's going to take thousands and thousands of patients to figure out if this agent is related or not, because look at the low natural

Page 168

history numbers.

Q. When you say in your paper a causal relationship has not been established conclusively, at what point, if ever, in the scientific community can a causal relationship be established conclusively?

A. Well, if we had a large enough case-control data study, you could be fairly certain within certain statistical limits that there was or was not a relationship; that is, you could say, well, there's a 95 percent chance we have excluded a causal relationship if we had this sample size of X, followed this many patients for Y, and here's the data we got. That's the best you're going to have. But for 100 percent, you're never going to have that.

Q. Do you know under what circumstances Pfizer has asked the University of Iowa to contribute in any prospective case-control study?

A. Well, they recruited all the major study centers. The University of Iowa obviously would be one that would want to be included in that. We went to the preliminary discussions. We saw the protocol. So I think almost all the major centers have seen the protocol; it's just a matter of participating, yes or no, and this is still -- the controversial debate is

Page 169

still going on.

Q. Where was the initial meeting held?

A. I can't remember. I want to say California, but I can't remember right now.

Q. Did you go out there on your own dime? Did you go to California on your own dime, or did the pharmaceutical company sponsor your trip?

A. No, I think there was some -- It was part of another meeting, and so the refreshments, et cetera, were provided, and then this presentation unfolded at our other meeting, so it was simultaneous to another meeting. People came on their own dime anyway, but it was informational.

Q. Were there any handouts presented by Pfizer with respect to the study?

A. Yeah, there were handouts.

Q. Do you have those? Do you still have those?

A. No, and I think we are asked to sign a confidentiality agreement on the details.

MR. RICHARDS: I think that's all I have.

JUDGE BORG: Ms. Leskin, anything?

MS. LESKIN: Yeah.

JUDGE BORG: Oh, time, 4:58. Ms. Leskin, anything?

Page 170

MS. LESKIN: Yes, just a few minutes' worth, Judge.

REDIRECT EXAMINATION

BY MS. LESKIN:

Q. I want to make sure I understood you correctly. Did I hear you correctly; did you apply a different standard when assessing legal causation versus scientific causation?

A. No. There's a difference in the standard that is accepted in the court of law. In this case my opinion was more likely than not. That would be a very difficult thing to use for life or death decisions in the clinic, so --

Q. Okay.

A. That's the difference in the standard, unless I'm not reading your -- the legal standard. I was asked the specific question is it more likely than not in this particular patient on the causality question. Yeah, it's more likely than not. That was the question that was posed to me. But it's different in the clinic.

Q. You use a different criteria in science, right?

A. Yeah, you can be much more rigorous, and that's why, as I mentioned in the articles, causality

Page 171

has not been established for this agent.

Q. Okay. If you can turn to Exhibit 16, which is the article you published, an expert review of ophthalmology following the Sally Letson symposium. It looks like this (indicating).

A. Yes. (Witness complies.) I should have kept them in order.

Q. That's okay. We'll put it back in order.

A. Yes.

Q. Now, you told me it was a little misleading not to look at the pro, because you only gave the con side.

A. Yes.

Q. This (indicating) was a summary of the presentation, right, that you wrote; this article, Exhibit 16?

A. Yes.

Q. And at the end of the day you took all the information that was given, and you wrote a summary of the entire symposium, correct?

A. Correct.

Q. And if you look at the third page in the left-hand column at the bottom, you talk about the presentation we've been talking about for a while today, right --

Page 172

A. Yes.

Q. -- the one with you and Dr. Sadun?

A. Yes.

Q. And you wrote, Sadun, pro, and Lee, con, debated the question of whether or not erectile dysfunction agents, e.g., Viagra, Pfizer, New York, USA, can cause nonarteritic anterior ischemic optic neuropathy. Although there is a biologically plausible mechanism, i.e., hypotension, and there have been several cases reported in the literature, a cause and effect relationship remains unproven. Did I read that correctly?

A. Yes.

Q. And that's a valid conclusion based on what was presented, correct?

A. Yes.

Q. And you stand by that today, correct?

A. Yes, only a prospective observational case-control study with sufficient power and sample size can answer this question on a population basis.

Q. And because it has not been proven, that's why Pfizer and Bayer, together with the FDA, are doing these studies that are going forward, correct?

A. That's the whole point. If we could rely upon everything that's been published before, why

Page 173

would you have to do another study --

Q. Right.

A. -- because it was either proven that it was or was not causal, and you wouldn't have to have another study, would you? So the fact that there are these little case-control studies, and there's all -- people like me giving their opinion, only a prospective large sample size case-control study can answer this question.

Q. And that hasn't been done yet?

A. It has not been done yet.

Q. You told us that you have not accessed the FDA database since the time of the presentation, correct?

A. I maybe looked at it, but not for this.

Q. Okay. And so the number of cases that are in that database, that's just a guess on your part, correct?

A. Yeah, I have no idea how many there are now.

Q. Okay. And you're not relying on that for your opinion in this case?

A. No. Like the last slide of my presentation, it's just more anecdotes.

Q. Okay.

Page 174

A. Forty-three cases, sixty-five cases.
Q. Counsel asked you when you started asking patients specifically about their use of PDE-5 inhibitors, and you said it was mid-2000s when the FDA warning -- right around the time of the FDA warning.
A. Yeah.
Q. And we marked that earlier, and that was July 2005, if you look at Exhibit 12.
A. Yeah. It's probably -- The FDA warning is not the time I would use. It's like somewhere around there, because that's when the buzz was starting to generate, and the people were starting to ask the question.
Q. So you didn't base your decision to start discussing this issue with your patients on the FDA statement, right?
A. No, because Dr. Pomeranz had already presented it, and it already had started to filter through the meetings that this might be a problem, so then people say, hey, maybe you should start asking about it, and then the lay press and then the FDA, so that's kind of the time line as it played out.
Q. And as a physician, you keep up with the

Page 175

current medical literature, is that fair?
A. Yeah. So there were already cases kind of trickling out before the FDA thing in '05.
Q. And there were cases trickling out before you started discussing it with your patients?
A. That's right.
Q. And there was a time that you were aware of these case reports, but you weren't discussing it with your patients, correct?
A. That's correct.
Q. Because it hadn't reached the point where there was sufficient information that it was worth talking to your patients about, is that fair to say?
A. That is true.
Q. So that scale, so to speak, that tipped over to when you started talking with your patients, just so I understand the time, that occurred, in your mind, based -- sometime in 2005, is that fair?
A. Maybe beforehand, because we had already heard about the case reports, et cetera, so I can't be precise on the date, year.
Q. So about when, two thousand -- give or take a year or two; was it more than that?
A. Yeah.
Q. Would it have been --

Page 176

A. That's fair.
Q. Okay. Do you know the design of the study that Pfizer is conducting on the issue of PDE-5 inhibitors and NAION?
A. Yeah, I believe it's an observational crossover. It's a unique design, so -- I'm not an expert on epidemiologic studies, but --
Q. Do you need to follow up patients for a significant -- for any period of time on a case-control crossover study?
A. That's one of the problems with the -- that was mentioned as what the debate is about, so you're looking backwards in time, but it's still considered prospective, because you're collecting data that's reliable, versus going forward in time from the start. So, yeah, this is a unique design. That's what is part of the problem. Many people complained that the uniqueness of the design was not a strict case-control prospective. But, yes -- The answer is, yes, we don't have to do as much.
Q. Have you discussed the study with any epidemiologist?
A. No, but the epidemiologist data was presented at the meeting, and that's been the subject of many e-mails along the NANOS chat line,

Page 177

criticizing the design and that the design might be designed to find no result, and that's why some of the places are not participating.
MS. LESKIN: I have no further questions.
MR. RICHARDS: I have a follow-up.
RECROSS EXAMINATION
BY MR. RICHARDS:
Q. Just to clarify, in 2006 when you provided this summary of the Sally Letson symposium, you said a cause and effect relationship remains unproven. That's in the scientific community, right?
A. That's correct.
Q. In the legal community the standard is more likely than not, so with respect to proving more likely than not, it has been proven in this case with Mr. Martin, right?
MS. LESKIN: Objection.
JUDGE BORG: Overruled.
A. Yes, I believe that the answer to the more likely than not question that was posed to me about this particular patient, given his circumstances and using the Austin Bradford Hill criteria on him, more likely than not the erectile dysfunction agent was the precipitating factor. But can you use Mr. Martin's case to prove a causal

Page 178

relationship for all of the cases in the world; no, because that remains unproven, and that needs to be answered with an observational prospective large sample size trial.

Q. If Mr. Martin's case can, by itself, establish causation in Mr. Martin, then by its nature you could, in turn, say that it could cause NAION in other folks; you would have to just look at their individual cases, right?

A. And that is precisely what we describe we do on every single patient that comes to us who has ischemic optic neuropathy who says they are on one of these agents. We go through this whole list, because that's really what the guy is asking, right; how much risk am I going to have of going blind from taking this? If they don't have any of the criteria, then I tell them the risk is low; if they have all the criteria, I say the risk is high, so for that particular patient more likely than not he should stop, but I can't just say for everybody more likely than not.

Q. You have to look at their individual case?

A. You have to look at individual cases. That's why the other case that was mentioned, I looked at that one, too, and I said, yeah, that's not so good.

Page 179

Q. Now, Mr. Pomeranz -- Dr. Pomeranz; you had mentioned he has some case reports before 2005. Those case reports that are circulated among the scientific community, in your experience that's not something that individual patients, who are not scientists, who don't work in the field, would have any buzz about, would you?

A. No, they wouldn't know that.

Q. They wouldn't know to ask their doctor whether or not there's a relationship between Viagra and NAION in 2002, because those are the only case reports, and only academics would look at that issue, right?

A. That's correct. That's why it's not appropriate to say, look, if he didn't mention it, he didn't mention it. Why would he -- Why would he mention that? Nowadays, of course, many more patients mention it. But even today if you don't ask men about the erectile dysfunction agents, they will not disclose this information voluntarily.

Q. Just so I'm -- Just so it's clear, if Viagra, in your opinion, was a precipitating factor in Mr. Martin's case, then you could extrapolate from there and say that it could be a precipitating factor in other patients as well, generally speaking, but you would have to look at each individual patient's case to make that determination, right?

Page 180

A. That's correct. Until we have prospective observational studies from an epidemiologic population basis, every one of these cases is going to have to be looked at on an individual basis.

JUDGE BORG: Is that it, Mr. Richards?

MS. LESKIN: One more -- One more question.

JUDGE BORG: Okay.

MR. RICHARDS: Yes, but we both take up on the same thing. We're both trying to maneuver now his testimony to fit our snippet in the sound byte from the --

JUDGE BORG: I don't think --

MS. LESKIN: Objection to the characterization.

JUDGE BORG: Go ahead.

FURTHER REDIRECT EXAMINATION

BY MS. LESKIN:

Q. Dr. Lee, have you done any studies evaluating the likelihood of men to discuss their Viagra use with their physician?

A. No. This is just based on my experience and my patient population, but I can tell you from my experience that when they list their medicines, and it's not on there, and then you say are you taking anything else; no; how about an erectile dysfunction agent; okay, maybe --

Page 181

Q. Okay.

A. -- once in a while.

Q. You haven't done any studies of that?

A. No.

Q. And you didn't talk to Mr. Martin about that?

A. No.

Q. And you don't know why or why not Mr. Martin discussed his Viagra use with his physician, is that a fair statement?

A. I don't know that.

MS. LESKIN: No questions -- more questions.

MR. RICHARDS: I'm done.

JUDGE BORG: Okay. Thanks, Dr. Lee.

MS. LESKIN: Thank you, Doctor. And thank you for moving us up to one o'clock. Off the record.

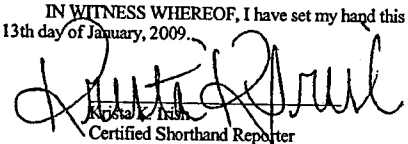
(Deposition concluded at 5:15 p.m.)

CERTIFICATE

I, Krista K. Irish, Certified Shorthand Reporter of the State of Iowa, do hereby certify that on the 13th day of January, 2009, at Hotel Vetro, 210 South Linn Street, Iowa City, Iowa, there appeared before me the following-named person, to wit: ANDREW LEE, M.D., who was by me first duly sworn to testify the truth, the whole truth, and nothing but the truth in the above-entitled cause; that I reported in shorthand the testimony of said witness, reduced the same to typewriting under my direction and supervision, and that the foregoing deposition is a true record of the testimony given by said witness and of all proceedings had on the taking of said deposition at the above time and place.

I further certify that I am not related to or employed by any of the parties to this deposition, and further that I am not a relative or employee of any attorney or counsel employed by the parties hereto or financially interested in the action.

IN WITNESS WHEREOF, I have set my hand this 13th day of January, 2009.



Krista K. Irish
Certified Shorthand Reporter
Registered Merit Reporter